

Designation Run Report

# Prevoznik 05060915

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Prevoznik, Thomas 04-17-2019  
Prevoznik, Thomas 04-18-2019  
Prevoznik, Thomas 05-17-2019

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**Defendants' Counter Designations 01:19:52**

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**Total Time 01:19:52**



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56:8 - 56:24	<p><b>Prevoznik, Thomas 04-17-2019 (00:01:00)</b></p> <p>56:8 Q. To your understanding, what  56:9 are the uses of the ARCOS data?  56:10 A. Well, it was originally for  56:11 UN reporting, so it was -- it's used for  56:12 UN reporting. It's used for quotas.  56:13 It's used to show trends. It's used in  56:14 our investigations, you know,  56:15 administrative, civil, criminal. It  56:16 supports investigations. We share it  56:17 with other federal agencies or state  56:18 agency, law enforcement, regulatory  56:19 agencies as well that are all, you know,  56:20 working to combat the diversion of  56:21 controlled substances. So it's working  56:22 with them in corroboration on  56:23 investigations. So it's used in various  56:24 means.</p>	V1.1
75:7 - 75:13	<p><b>Prevoznik, Thomas 04-17-2019 (00:00:18)</b></p> <p>75:7 Q. With respect to the  75:8 distributor initiative, is it fair to say  75:9 the early years of the distributor  75:10 initiative, the individuals that attended  75:11 the distributor meetings were Kyle Wright  75:12 and Michael Mapes?  75:13 A. Yes.</p>	V1.2
75:17 - 76:8	<p><b>Prevoznik, Thomas 04-17-2019 (00:00:48)</b></p> <p>75:17 Q. And then in -- who were the  75:18 individuals from the DEA that were  75:19 primarily attending the distributor  75:20 briefings in the '08, '09, and '10 time  75:21 period?  75:22 A. It would still be Kyle, Kyle  75:23 Wright. Lisa Sullivan. Dave White. And  75:24 then Lenny Levin. Lenny Levin.  76:1 Q. In that time period, you  76:2 were still in the field offices or  76:3 training, so you would not have attended  76:4 any of the distributor briefings  76:5 personally --</p>	V1.3

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82:1 - 83:20

76:6 A. Correct.

76:7 Q. -- Mr. Prevoznik?

76:8 A. Correct.

**Prevoznik, Thomas 04-17-2019 (00:01:45)**

V1.4

82:1 Q. You were a -- you were also

82:2 a diversion investigator from

82:3 February '91 to September of 2001,

82:4 correct?

82:5 A. Correct.

82:6 Q. And was your role from

82:7 February '91 to September 2001 the same

82:8 as you have generally described it from

82:9 when you were a diversion investigator in

82:10 2006 to 2008?

82:11 A. Correct.

82:12 Q. Now, for part of that time

82:13 period, as a diversion investigator, did

82:14 you receive and review excessive purchase

82:15 reports?

82:16 A. Excessive purchase reports?

82:17 Q. Yes.

82:18 A. Yes.

82:19 Q. And describe for me what an

82:20 excessive purchase report is.

82:21 A. An excessive purchase

82:22 report, it's an after -- it's a

82:23 transaction that has already occurred.

82:24 So it's sales data that it -- that was

83:1 provided by the registrants. So we would

83:2 review it when it came in.

83:3 Again, we would separate it

83:4 by AORs. If -- you know, if I'm in

83:5 Philadelphia, and I had stuff in New

83:6 Jersey, I would separate and send New

83:7 Jersey theirs. And if we had Pittsburgh

83:8 stuff we would send Pittsburgh their

83:9 stuff. Maryland got their stuff. So we

83:10 would review that.

83:11 Q. And the excessive purchase

83:12 reports were coming in primarily from

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	83:13 distributors?	
	83:14 A. Yeah, primarily.	
	83:15 Q. And did you -- and so you	
	83:16 investigated excessive purchase reports	
	83:17 when they came in?	
	83:18 A. Yeah, we would review them.	
	83:19 And then we would take action if we	
	83:20 deemed it necessary.	
85:9 - 85:14	<b>Prevoznik, Thomas 04-17-2019 (00:00:15)</b>	V1.5
	85:9 Is it fair to say that the	
	85:10 excessive purchase reports continued to	
	85:11 be received by field offices till	
	85:12 sometime in the 2008 time period?	
	85:13 A. Yeah. We would still get	
	85:14 them.	
94:2 - 94:7	<b>Prevoznik, Thomas 04-17-2019 (00:00:12)</b>	V1.6
	94:2 Q. So -- well, let me -- let me	
	94:3 ask it this -- when do you recall the DEA	
	94:4 first began receiving excessive purchase	
	94:5 reports?	
	94:6 A. I remember them when I first	
	94:7 got into Philadelphia in 1991.	
117:7 - 117:11	<b>Prevoznik, Thomas 04-17-2019 (00:00:14)</b>	V1.7
	117:7 Q. The DEA today does not	
	117:8 necessarily endorse or bless a particular	
	117:9 system for suspicious order reporting,	
	117:10 correct?	
	117:11 A. Correct.	
121:15 - 121:19	<b>Prevoznik, Thomas 04-17-2019 (00:00:14)</b>	V1.8
	121:15 Q. Now, as you've described,	
	121:16 did the -- the DEA understood that the	
	121:17 excessive purchase reports listed orders	
	121:18 that had already been shipped, correct?	
	121:19 A. Correct.	
122:1 - 122:12	<b>Prevoznik, Thomas 04-17-2019 (00:00:39)</b>	V1.9
	122:1 Q. Okay. And are you familiar	
	122:2 with the fact that the December 2007	
	122:3 Rannazzisi letter advised the industry	
	122:4 that they should no longer submit	
	122:5 excessive order reports?	

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	122:6 A. Yes.	
	122:7 Q. Prior to 2007, did the	
	122:8 administration, the DEA administration,	
	122:9 issue any guidance to the industry	
	122:10 stating that excessive order reports	
	122:11 should not be submitted?	
	122:12 A. I am not aware of any.	
126:18 - 126:22	<b>Prevoznik, Thomas 04-17-2019 (00:00:08)</b>	V1.10
	126:18 Q. We've already established	
	126:19 that prior to 2007 you're not aware of	
	126:20 the DEA saying, no more excessive	
	126:21 purchase reports, right?	
	126:22 A. Right. Correct.	
127:7 - 127:12	<b>Prevoznik, Thomas 04-17-2019 (00:00:14)</b>	V1.11
	127:7 Q. And the DEA was aware that	
	127:8 there were, in fact, being routinely	
	127:9 submitted by distributors excessive	
	127:10 purchase reports on a regular basis,	
	127:11 right?	
	127:12 A. We were aware.	
130:13 - 131:23	<b>Prevoznik, Thomas 04-17-2019 (00:01:30)</b>	V1.12
	130:13 Q. So as part of the audit	
	130:14 process, operating systems that are	
	130:15 designed to review suspicious orders are	
	130:16 reviewed by the DEA?	
	130:17 A. Well, it's not just the	
	130:18 schedule. I mean it could be a	
	130:19 pre-registration, somebody is coming on	
	130:20 and they have -- we have to go through	
	130:21 the whole public interest of, you know,	
	130:22 what do you have in place to operate and	
	130:23 detect a system. So it's not just a	
	130:24 schedule investigation. There are	
	131:1 schedule investigations that we follow	
	131:2 up, and we do that as well. So it comes	
	131:3 in -- it comes in various times that	
	131:4 we're going to review somebody's	
	131:5 operating system, whether we're on	
	131:6 schedule investigation, or whether we're	
	131:7 doing an investigation on a pharmacy or	

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131:8 something like that, where we're going to  
 131:9 look at how many SORs were submitted or  
 131:10 not submitted, or we're going to look at  
 131:11 the ARCOS data, how much did they buy.  
 131:12 We're going to look at  
 131:13 various things to make the determination  
 131:14 on what is going on.

131:15 Q. And if either in the  
 131:16 pre-registration process or in the audit  
 131:17 process the DEA determines that a  
 131:18 registrant's system is not adequately  
 131:19 detecting suspicious orders, is that  
 131:20 something that is conveyed to the  
 131:21 registrant?

131:22 A. Yeah, we -- we would tell  
 131:23 them, you need to add something.

134:2 - 134:9

**Prevoznik, Thomas 04-17-2019 (00:00:17)**

V1.13

134:2 Q. Exhibit 5 is a December 27,  
 134:3 2007, letter written by Joseph Rannazzisi  
 134:4 on behalf of the DEA to registrants,  
 134:5 correct?

D106.1.2

D106.2.1

134:6 A. Correct.

134:7 Q. And this letter was sent  
 134:8 industrywide; is that right?

134:9 A. Correct.

136:17 - 137:2

**Prevoznik, Thomas 04-17-2019 (00:00:36)**

V1.14

D106.1.2

136:17 Q. Prior to December 27th,  
 136:18 2007, the date of this Rannazzisi letter,  
 136:19 had the agency issued any written  
 136:20 guidance to the industry stating that  
 136:21 excessive purchase reports did not comply  
 136:22 with the requirements the industry had  
 136:23 under 21 C.F.R. Section 1301.74?

136:24 A. I'm not aware.

137:1 Q. Now, the DEA also says in  
 137:2 the last sentence of the second

D106.1.1

137:3 - 137:10

**Prevoznik, Thomas 04-17-2019 (00:00:20)**

V1.15

137:3 paragraph, "Past communications with DEA,  
 137:4 whether implicit or explicit, that could  
 137:5 be construed as approval of a particular

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	137:6 system for reporting suspicious orders, 137:7 should no longer be taken to mean that 137:8 DEA approves a specific system." 137:9 Do you see that? 137:10 A. Yes.	clear
143:1 - 143:7	<b>Prevoznik, Thomas 04-17-2019 (00:00:16)</b>	V1.16
	143:1 Q. Is it fair to say that in 143:2 time periods prior to 2008, there were 143:3 communications that the DEA had with 143:4 certain registrants, whether implicit or 143:5 explicit, that could be construed as 143:6 approval of a particular system for 143:7 reporting suspicious orders?	
143:12 - 143:12	<b>Prevoznik, Thomas 04-17-2019 (00:00:01)</b>	V1.17
	143:12 THE WITNESS: Yes.	
157:18 - 157:20	<b>Prevoznik, Thomas 04-17-2019 (00:00:08)</b>	V1.18
	157:18 Q. Now, you referenced internet 157:19 pharmacies becoming a big problem at some 157:20 point in time, correct?	
157:23 - 158:3	<b>Prevoznik, Thomas 04-17-2019 (00:00:19)</b>	V1.19
	157:23 THE WITNESS: Correct. 157:24 BY MS. MAINIGI:	
	158:1 Q. And did the advent of 158:2 internet pharmacies bring about a greater 158:3 problem with controlled substances?	
158:6 - 158:9	<b>Prevoznik, Thomas 04-17-2019 (00:00:06)</b>	V1.20
	158:6 THE WITNESS: I believe what 158:7 I said, it went from a 158:8 local/regional issue to a national 158:9 issue.	
158:10 - 158:21	<b>Prevoznik, Thomas 04-17-2019 (00:00:30)</b>	V1.21
	158:10 BY MS. MAINIGI: 158:11 Q. The internet pharmacy 158:12 problem caused the DEA, or prompted the 158:13 DEA to launch the internet distributor 158:14 initiative in late 2005, correct? 158:15 A. Yes. 158:16 Q. And the purpose of the 158:17 initiative was to educate DEA registrants 158:18 regarding their obligations and possible	

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162:23 - 164:14	<p>158:19 role in supplying internet pharmacies; is</p> <p>158:20 that right?</p> <p>158:21 A. Yes.</p> <p><b>Prevoznik, Thomas 04-17-2019 (00:01:37)</b></p> <p>162:23 Q. In terms of the trends and</p> <p>162:24 the emphasis, you said you're still doing</p> <p>163:1 distributor initiative meetings through</p> <p>163:2 today, right?</p> <p>163:3 A. I don't know if we have any</p> <p>163:4 today. But we've done some recently,</p> <p>163:5 yes.</p> <p>163:6 Q. Okay. The more recent ones,</p> <p>163:7 where is the focus and where is the</p> <p>163:8 trends?</p> <p>163:9 A. Well, I think what we've</p> <p>163:10 been showing, and as it's been reported,</p> <p>163:11 we're seeing a decline in the number of</p> <p>163:12 opioid prescriptions. We've seen</p> <p>163:13 increase in amphetamines and</p> <p>163:14 methylphenidate. We're seeing -- the one</p> <p>163:15 opioid we still see an increase in is</p> <p>163:16 Suboxone, buprenorphine, for drug</p> <p>163:17 treatment. We're seeing a little bit of</p> <p>163:18 shift of the drugs.</p> <p>163:19 Q. So the trends and the</p> <p>163:20 problem areas are unfortunately always</p> <p>163:21 changing and shifting. Is that fair?</p> <p>163:22 A. Well, there tends to be a</p> <p>163:23 shift, yeah.</p> <p>163:24 Q. And the DEA does its best to</p> <p>164:1 try to identify the changes and the</p> <p>164:2 shifts in the trends, correct?</p> <p>164:3 A. Well, I mean, the data --</p> <p>164:4 the data shows that, so it's not DEA</p> <p>164:5 doing it. You know, there's been a lot</p> <p>164:6 of hard work by a lot -- a lot of</p> <p>164:7 different people, including the industry.</p> <p>164:8 So...</p> <p>164:9 Q. The data from the industry</p> <p>164:10 helps everyone identify the shifts in the</p>	V1.22
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	164:11 trends, correct?	
	164:12 A. Yeah.	
	164:13 Q. Including the DEA?	
	164:14 A. Yeah. Yes.	
167:5 - 167:12	<b>Prevoznik, Thomas 04-17-2019 (00:00:18)</b>	V1.23
	167:5 Q. Did the Controlled	
	167:6 Substances Act contain any language that	
	167:7 states whether or not a distributor could	
	167:8 ship a suspicious order?	
	167:9 A. It doesn't say specifically	
	167:10 that. It does say that it needs to be --	
	167:11 it has to maintain -- maintain effective	
	167:12 control against diversion.	
170:19 - 170:24	<b>Prevoznik, Thomas 04-17-2019 (00:00:18)</b>	V1.24
	170:19 Q. Are you generally aware from	
	170:20 all the people that you talked to at the	
	170:21 DEA, are you generally aware as the DEA,	
	170:22 that in the '07-'08 time period, there	
	170:23 was confusion in the industry as to the	
	170:24 meaning of the do-not-ship policy?	
171:3 - 172:5	<b>Prevoznik, Thomas 04-17-2019 (00:01:05)</b>	V1.25
	171:3 THE WITNESS: For the people	
	171:4 I talked to? I'm just trying to	
	171:5 remember what we -- what we talked	
	171:6 about.	
	171:7 It was -- from my	
	171:8 recollection of talking to the	
	171:9 folks was that again it was a	
	171:10 business decision on whether to	
	171:11 ship or not ship. That we, DEA	
	171:12 were not going to direct a	
	171:13 registrant don't ship or not ship	
	171:14 at that time.	
	171:15 BY MS. MAINIGI:	
	171:16 Q. In 2008?	
	171:17 A. So -- I'm sorry, 2 -- no,	
	171:18 that was prior to that. Because in -- in	
	171:19 '7 that's when it came out that --	
	171:20 Q. So in '7 it was clear that	
	171:21 you were now directing registrants do not	

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	171:22 ship?	
	171:23 A. Right. Because of --	
	171:24 because of the internet.	
	172:1 Q. And prior to 2 --	
	172:2 December 2007 it was a business decision	
	172:3 by each registrant recognizing what their	
	172:4 own obligations were?	
	172:5 A. Correct.	
175:7 - 175:20	<b>Prevoznik, Thomas 04-17-2019 (00:00:36)</b>	V1.26
	175:7 Q. Okay. So in '05, '06 and	
	175:8 '07, as I understand it from Mr. Wright's	
	175:9 testimony, he and Mr. Mapes primarily	
	175:10 handled the distributor initiative	
	175:11 briefings, correct?	
	175:12 A. Correct.	
	175:13 Q. And you have talked to	
	175:14 neither Mr. Wright nor Mr. Mapes,	
	175:15 correct?	
	175:16 A. Correct.	
	175:17 Q. So you don't know sitting	
	175:18 here today what Mr. Mapes or Mr. Wright	
	175:19 said or heard in those distributor	
	175:20 initiative briefings, correct?	
175:23 - 175:23	<b>Prevoznik, Thomas 04-17-2019 (00:00:01)</b>	V1.27
	175:23 THE WITNESS: No.	
177:15 - 178:5	<b>Prevoznik, Thomas 04-17-2019 (00:00:48)</b>	V1.28
	177:15 Q. After this Rannazzisi	
	177:16 letter, the December 2007 Rannazzisi	
	177:17 letter, did DEA provide any guidance to	
	177:18 registrants as to how to design or	
	177:19 implement their suspicious order	
	177:20 monitoring systems?	
	177:21 A. Well, yeah, with the MOAs	
	177:22 that we -- and settlements that we got	
	177:23 with them.	
	177:24 Q. And in the MOA meetings, you	
	178:1 provided guidance as to what your	
	178:2 expectations were as to the suspicious	
	178:3 order monitoring systems going forward,	
	178:4 correct?	

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178:19 - 178:23	<p>178:5 A. That's where we -- yes.</p> <p><b>Prevoznik, Thomas 04-17-2019 (00:00:19)</b></p> <p>178:19 Q. So essentially there was no</p> <p>178:20 industrywide guidance that was provided</p> <p>178:21 in 2008 or forward as to how to design or</p> <p>178:22 implement suspicious order monitoring</p> <p>178:23 systems, true?</p>	V1.29
179:2 - 179:3	<p><b>Prevoznik, Thomas 04-17-2019 (00:00:03)</b></p> <p>179:2 THE WITNESS: Nationwide,</p> <p>179:3 correct.</p>	V1.30
179:22 - 180:11	<p><b>Prevoznik, Thomas 04-17-2019 (00:00:30)</b></p> <p>179:22 Q. Now, does the DEA agree that</p> <p>179:23 there's more than one way to design and</p> <p>179:24 operate a system that can identify and</p> <p>180:1 report suspicious orders?</p> <p>180:2 A. Yes.</p> <p>180:3 Q. And there's no single</p> <p>180:4 feature that makes a suspicious order</p> <p>180:5 monitoring system compliant, correct?</p> <p>180:6 A. Correct.</p> <p>180:7 Q. And the DEA leaves it up to</p> <p>180:8 the registrant to design a system that</p> <p>180:9 works with its own business model and</p> <p>180:10 customer base, correct?</p> <p>180:11 A. Correct.</p>	V1.31
182:12 - 182:15	<p><b>Prevoznik, Thomas 04-17-2019 (00:00:13)</b></p> <p>182:12 Q. Is the review -- is it fair</p> <p>182:13 to say then that the identification of</p> <p>182:14 suspicious orders can be a subjective</p> <p>182:15 process?</p>	V1.32
182:18 - 183:5	<p><b>Prevoznik, Thomas 04-17-2019 (00:00:22)</b></p> <p>182:18 THE WITNESS: What do you</p> <p>182:19 mean by "subjective"?</p> <p>182:20 BY MS. MAINIGI:</p> <p>182:21 Q. Well, do you understand the</p> <p>182:22 meaning of the word "subjective"?</p> <p>182:23 A. I'm asking you in terms of</p> <p>182:24 this, what do you mean by subjective?</p> <p>183:1 Q. Well, what I mean is that</p> <p>183:2 you and I looking at the same data,</p>	V1.33

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183:12 - 183:15	183:3 sometimes, not always, may come to 183:4 different conclusions, as to whether an 183:5 order is suspicious. Is that possible? <b>Prevoznik, Thomas 04-17-2019 (00:00:12)</b>	V1.34
183:18 - 183:22	183:12 A. That is possible. 183:13 Q. And so, therefore, the 183:14 identification of suspicious orders is a 183:15 somewhat subjective process? <b>Prevoznik, Thomas 04-17-2019 (00:00:10)</b>	V1.35
185:1 - 185:2	183:18 THE WITNESS: I mean, when 183:19 it comes down to a suspicious 183:20 orders, what is triggering may -- 183:21 it's the whole point of the 183:22 suspicious order is to identify -- <b>Prevoznik, Thomas 04-17-2019 (00:00:01)</b>	V1.36
190:18 - 190:24	185:1 THE WITNESS: Yeah, it can 185:2 be subjective. <b>Prevoznik, Thomas 04-17-2019 (00:00:25)</b>	V1.37
191:3 - 191:15	190:18 Did DEA understand that in 190:19 the aftermath of Mr. Rannazzisi's 190:20 December 27, 2007, letter, that 190:21 distributors took actions that resulted 190:22 in a number of complaints by pharmacies 190:23 that distributors were acting 190:24 precipitously? <b>Prevoznik, Thomas 04-17-2019 (00:00:32)</b>	V1.38
191:18 - 192:10	191:3 THE WITNESS: We -- we heard 191:4 complaints. 191:5 BY MS. MAINIGI: 191:6 Q. Complaints from whom? 191:7 A. From -- it could be 191:8 pharmacies. It could be -- it could be 191:9 patients saying I can't get my meds. 191:10 Q. And so there were complaints 191:11 from pharmacies, kind of the variety we 191:12 see in Exhibit 6, basically saying 191:13 distributors are taking actions that are 191:14 unfair to the pharmacies as a result of 191:15 Mr. Rannazzisi's letter, true? <b>Prevoznik, Thomas 04-17-2019 (00:00:27)</b>	D1894.3 D1894.3.1  clear V1.39

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	191:18 THE WITNESS: I'm not sure 191:19 that it's just the letter, because 191:20 this was also the time that we 191:21 started getting into settlement 191:22 agreements with the industry as 191:23 well. So it wasn't just the 191:24 letter. It was...	
	192:1 BY MS. MAINIGI: 192:2 Q. But there was -- I'm sorry. 192:3 A. No. Go ahead. 192:4 Q. But there was -- and so 192:5 there were complaints from pharmacies to 192:6 the DEA, correct? 192:7 A. Correct. 192:8 Q. And there were complaints 192:9 from patients to the DEA also, correct? 192:10 A. Yeah.	
194:8 - 194:10	<b>Prevoznik, Thomas 04-17-2019 (00:00:12)</b> 194:8 Q. So was the perception of 194:9 some in the market that the distributors 194:10 had overreacted to what DEA was saying?	V1.40
194:13 - 195:21	<b>Prevoznik, Thomas 04-17-2019 (00:01:04)</b> 194:13 THE WITNESS: I -- I don't 194:14 know what the wholesalers were 194:15 thinking. I -- if -- I mean, I 194:16 know from my own experience with 194:17 the -- with the pharmacy diversion 194:18 awareness conferences where we had 194:19 pharmacists coming up and saying 194:20 hey, they are putting thresholds 194:21 on, they are cutting us off, this 194:22 is affecting patient care. And 194:23 they said well, DEA sets the 194:24 threshold. And we said, no, 195:1 that's not true, we did not set 195:2 the thresholds. The industry sets 195:3 the thresholds. 195:4 That was an eye-opener for 195:5 them, because they were being 195:6 told -- somebody was telling them	V1.41

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	<p>195:7 the DEA set thresholds. We don't</p> <p>195:8 set thresholds on that -- on that</p> <p>195:9 part, with -- in regards to that.</p> <p>195:10 So, pushing back, you know,</p> <p>195:11 and then you get -- then we -- we</p> <p>195:12 take action against pharmacists,</p> <p>195:13 you have a similar situation with</p> <p>195:14 a pharmacist saying oh, the DEA</p> <p>195:15 said we're not allowed to fill</p> <p>195:16 these prescriptions. DEA does</p> <p>195:17 not -- does not regulate the</p> <p>195:18 practice of medicine. And,</p> <p>195:19 those -- you know, that's the</p> <p>195:20 pharmacist's decision whether to</p> <p>195:21 fill the prescription or not.</p>	
196:15 - 197:2	<b>Prevoznik, Thomas 04-17-2019 (00:00:28)</b>	V1.42
	<p>196:15 Q. And so the collective</p> <p>196:16 actions of DEA, including the Rannazzisi</p> <p>196:17 letter, including the settlements and so</p> <p>196:18 forth in 2007, you noticed an increase in</p> <p>196:19 complaints from pharmacists from seasoned</p> <p>196:20 patients in 2008, for example?</p> <p>196:21 A. Yes.</p> <p>196:22 Q. It was not DEA's intention</p> <p>196:23 to interfere with patients' ability to</p> <p>196:24 fill legitimate prescriptions for</p> <p>197:1 controlled substances, correct?</p> <p>197:2 A. Correct.</p>	
212:1 - 212:8	<b>Prevoznik, Thomas 04-17-2019 (00:00:18)</b>	V1.43
	<p>212:1 Q. Today, does the regulation</p> <p>212:2 explicitly reference knowing your</p> <p>212:3 customer?</p> <p>212:4 A. No.</p> <p>212:5 Q. Has DEA ever approved or</p> <p>212:6 endorsed any specific methodology to be</p> <p>212:7 used by manufacturers or distributors to</p> <p>212:8 know their customers?</p>	
212:11 - 212:17	<b>Prevoznik, Thomas 04-17-2019 (00:00:14)</b>	V1.44
	<p>212:11 THE WITNESS: Can you please</p> <p>212:12 repeat?</p>	

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	212:13 BY MS. MAINIGI:	
	212:14 Q. Sure. Has DEA ever approved	
	212:15 or endorsed any specific methodology to	
	212:16 be used by manufacturers or distributors	
	212:17 to know their customer?	
212:20 - 212:20	<b>Prevoznik, Thomas 04-17-2019 (00:00:01)</b>	V1.45
	212:20 THE WITNESS: No.	
216:4 - 216:10	<b>Prevoznik, Thomas 04-17-2019 (00:00:14)</b>	V1.46
	216:4 To your knowledge the DEA	
	216:5 has not issued any best practices	
	216:6 regarding what methodology to use to know	
	216:7 your customer to distributors and	
	216:8 manufacturers in the controlled	
	216:9 substances context?	
	216:10 A. Correct.	
219:21 - 220:1	<b>Prevoznik, Thomas 04-17-2019 (00:00:12)</b>	V1.47
	219:21 Q. So the DEA has in fact	
	219:22 issued written guidance on knowing your	
	219:23 customer in the chemical context,	
	219:24 correct?	
	220:1 A. Correct.	
220:5 - 220:10	<b>Prevoznik, Thomas 04-17-2019 (00:00:12)</b>	V1.48
	220:5 BY MS. MAINIGI:	
	220:6 Q. The DEA has not issued	
	220:7 written guidance elaborating on best	
	220:8 practices or methodology for knowing your	
	220:9 customer in the controlled substances	
	220:10 context, correct?	
220:13 - 220:16	<b>Prevoznik, Thomas 04-17-2019 (00:00:03)</b>	V1.49
	220:13 THE WITNESS: I believe --	
	220:14 BY MS. MAINIGI:	
	220:15 Q. I think that's a yes or no?	
	220:16 A. Correct, correct, correct.	
231:9 - 231:12	<b>Prevoznik, Thomas 04-17-2019 (00:00:09)</b>	V1.50
	231:9 Q. Is it fair to say that the	
	231:10 general view of DEA is that the	
	231:11 distributors would like to be in	
	231:12 compliance?	
231:17 - 231:24	<b>Prevoznik, Thomas 04-17-2019 (00:00:13)</b>	V1.51
	231:17 THE WITNESS: Yes. Yes, I	

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231:18 believe they do.

231:19 BY MS. MAINIGI:

231:20 Q. And certainly as you are

231:21 aware, from time to time, they have

231:22 reached out to the DEA seeking

231:23 clarification and further guidance,

231:24 correct?

232:3 - 232:6

**Prevoznik, Thomas 04-17-2019 (00:00:04)**

V1.52

232:3 THE WITNESS: I'm not -- I'm

232:4 not sure of what specific topics,

232:5 if you have a specific topic in

232:6 mind. But yes, they do reach out.

232:22 - 233:19

**Prevoznik, Thomas 04-17-2019 (00:00:48)**

V1.53

232:22 In that 2008 to 2013 time

232:23 period that we've focused on, is it fair

232:24 to say that when registrants such as

233:1 distributors and their trade associations

233:2 have reached out to seek clarification,

233:3 that sometimes DEA has not been able to

233:4 provide clarification?

233:5 A. So in this time frame is

233:6 2008 to 2013?

233:7 Q. Correct.

233:8 A. Which was the time when we

233:9 were investigating and litigating? Yeah,

233:10 that -- we -- we did not talk at that

233:11 point.

233:12 Q. You did not talk to

233:13 distributors in the 2008 to 2013 time

233:14 period generally?

233:15 A. Well, yeah, I mean up until

233:16 2010 we were doing the distributor

233:17 initiative. And then we stopped that for

233:18 a period because of the litigations and

233:19 the investigations going on.

235:2 - 235:9

**Prevoznik, Thomas 04-17-2019 (00:00:15)**

V1.54

235:2 Q. Since 2017, has the DEA

235:3 provided distributors with any additional

235:4 guidance on suspicious order

235:5 monitoring --



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235:6	A. I don't --	
235:7	Q. Written guidance.	
235:8	A. Not written guidance that	
235:9	I'm aware of.	
235:10 - 235:14	<b>Prevoznik, Thomas 04-17-2019 (00:00:16)</b>	V1.55
235:10	Q. There was some discussion in	
235:11	the last several years of a modification	
235:12	to the suspicious order regulation,	
235:13	correct?	
235:14	A. Correct.	
262:24 - 263:3	<b>Prevoznik, Thomas 04-17-2019 (00:00:07)</b>	V1.56
262:24	Q. And DEA is aware that the	
263:1	distributors programs, they set a monthly	
263:2	threshold for a customer's controlled	
263:3	substances purchases?	
263:6 - 263:12	<b>Prevoznik, Thomas 04-17-2019 (00:00:10)</b>	V1.57
263:6	THE WITNESS: To my	
263:7	knowledge, yes.	
263:8	BY MR. EPPICH:	
263:9	Q. And DEA never instructed	
263:10	distributors to set a monthly threshold	
263:11	at a specific level, did they?	
263:12	A. No.	
303:19 - 304:1	<b>Prevoznik, Thomas 04-17-2019 (00:00:13)</b>	V1.58
303:19	Q. You would agree with me that	
303:20	the statute itself does not contain the	
303:21	express instruction that a registrant	
303:22	should hold an order and not ship it if	
303:23	it determines it to be suspicious,	
303:24	correct?	
304:1	A. Correct.	
306:1 - 306:4	<b>Prevoznik, Thomas 04-17-2019 (00:00:09)</b>	V1.59
306:1	Does every order that's	
306:2	unusually large necessarily lead to	
306:3	diversion?	
306:4	A. I have no idea.	
306:7 - 306:8	<b>Prevoznik, Thomas 04-17-2019 (00:00:04)</b>	V1.60
306:7	THE WITNESS: I have no idea	
306:8	what you mean by unusually large.	
307:18 - 307:22	<b>Prevoznik, Thomas 04-17-2019 (00:00:14)</b>	V1.61

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307:18	Q. Okay. I do -- I do want to	
307:19	get back to my original question though,	
307:20	which was, is an order that is unusually	
307:21	large, does that order necessarily lead	
307:22	to diversion?	
308:1 - 308:5	<b>Prevoznik, Thomas 04-17-2019 (00:00:08)</b>	V1.62
308:1	THE WITNESS: It may or	
308:2	may -- it may or may not.	
308:3	BY MR. O'CONNOR:	
308:4	Q. Would the same be true of an	
308:5	unusually frequent order?	
308:8 - 308:13	<b>Prevoznik, Thomas 04-17-2019 (00:00:05)</b>	V1.63
308:8	THE WITNESS: Correct. It	
308:9	may or may not.	
308:10	BY MR. O'CONNOR:	
308:11	Q. And the same would be true	
308:12	of an order that deviates substantially	
308:13	from the normal pattern?	
308:16 - 308:17	<b>Prevoznik, Thomas 04-17-2019 (00:00:01)</b>	V1.64
308:16	THE WITNESS: Correct. It	
308:17	may or may not.	
309:4 - 309:6	<b>Prevoznik, Thomas 04-17-2019 (00:00:04)</b>	V1.65
309:4	Q. Not every suspicious order	
309:5	leads to diversion, correct?	
309:6	A. Correct.	
317:10 - 318:7	<b>Prevoznik, Thomas 04-17-2019 (00:00:53)</b>	V1.66
317:10	Q. All right. I'd like to go	
317:11	back to Exhibit 4, which you should still	
317:12	have a copy of.	
317:13	A. Which one is that?	
317:14	Q. Exhibit 4.	D107.1
317:15	A. Got it.	
317:16	Q. And do you recognize this	
317:17	document?	
317:18	A. Yes.	
317:19	Q. What -- what is it?	
317:20	A. It's the report to the U.S.	D107.1.1
317:21	Attorney General regarding the suspicious	
317:22	orders task force under the Comprehensive	
317:23	Methamphetamine -- Methamphetamine	

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	317:24 Control Act of 1996.	
	318:1 Q. Okay. I'm going to direct	
	318:2 your attention to the page that ends in	
	318:3 2212. It's towards the beginning.	D107.6
	318:4 A. I'm sorry. What was the	
	318:5 last number?	
	318:6 Q. 2212.	
	318:7 A. Okay.	
318:8 - 319:21	<b>Prevoznik, Thomas 04-17-2019 (00:01:31)</b>	V1.67
	318:8 Q. And specifically, the first	
	318:9 full paragraph that begins, "The task	D107.6.1
	318:10 force concluded that a single listing of	
	318:11 meaningful numerical parameters would be	
	318:12 difficult for the majority of registrants	
	318:13 which do not have highly automated	
	318:14 computer systems" -- "computer ordering	
	318:15 and tracking systems, the indicators	
	318:16 contained in Appendix A" -- exhibit --	
	318:17 and it's hard to read -- "represent	
	318:18 expanded guidance to be considered."	
	318:19 Then it continues. "For	D107.6.2
	318:20 the" -- "For the segments of industry who	
	318:21 have highly automated ordering and	
	318:22 tracking systems, the task force	
	318:23 recommends a system which starts with	
	318:24 quantifiable parameters which track	
	319:1 frequency of orders, deviation from prior	
	319:2 orders, and size of orders. See Appendix	
	319:3 A, Exhibit 2."	
	319:4 When this document talks	
	319:5 about recommending a system, they are	D107.6.3
	319:6 talking about a suspicious order	
	319:7 monitoring system, correct?	
	319:8 A. Right. For chemicals, List	
	319:9 1 chemicals.	
	319:10 Q. Okay. But it is a	
	319:11 suspicious order monitoring system,	
	319:12 agree?	
	319:13 A. Yes.	
	319:14 Q. Okay. And it says, "See	

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	319:15 Exhibit" -- I'm sorry. Strike that.	
	319:16 It says, "See Appendix A,	D107.6.4
	319:17 Exhibit 2."	
	319:18 Let's turn there.	
	319:19 A. Okay.	
	319:20 Q. And I can tell you the	
	319:21 number at the bottom ends in 2247.	D107.41
319:22 - 320:20	<b>Prevoznik, Thomas 04-17-2019 (00:00:50)</b>	V1.68
	319:22 A. Okay. 2247?	
	319:23 Q. 2247.	
	319:24 A. Okay.	
	320:1 Q. So that sentence referring	
	320:2 to suspicious order monitoring refers to	
	320:3 this exhibit.	
	320:4 Could you please read the	
	320:5 first five lines starting with,	
	320:6 "Exhibit 2."	D107.41.1
	320:7 A. Under terms and definition	
	320:8 or above?	
	320:9 Q. Above.	
	320:10 A. "Suspicious order reporting	
	320:11 system of 1998 for use in automated	
	320:12 tracking systems. The current	
	320:13 calculation being used for List 1	
	320:14 chemicals and Schedule II through V	
	320:15 controlled substances."	
	320:16 Q. Okay. So according to that	
	320:17 title, the calculation that's discussed	
	320:18 in this exhibit is being used for	
	320:19 Schedule II through V controlled	
	320:20 substances, correct?	
320:22 - 321:13	<b>Prevoznik, Thomas 04-17-2019 (00:00:49)</b>	V1.69
	320:22 THE WITNESS: That's what it	
	320:23 says. Yes, that's what it says.	
	320:24 BY MR. O'CONNOR:	
	321:1 Q. And looking down to Number	
	321:2 4, where it says "Note:" Could you	D107.41.2
	321:3 please read that sentence?	
	321:4 A. "Note: Factor equals 3 for	
	321:5 C-II and C-III controlled substances	

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	326:9 sorts of information does ARCOS contain?	
	326:10 A. ARCOS contains the	
	326:11 manufacturers and distributors that are	
	326:12 to report all transactions for	
	326:13 Schedule I, Schedule II, Schedule III	
	326:14 narcotics, and GHB, and manufacturers	
	326:15 also have reported -- additional	
	326:16 reporting requirements for some	
	326:17 psychotropics.	
326:24 - 327:4	<b>Prevoznik, Thomas 04-17-2019 (00:00:13)</b>	V1.72
	326:24 Q. Would ARCOS contain all the	
	327:1 distributions of prescription opioids	
	327:2 from distributors to pharmacies or other	
	327:3 retail outlets?	
	327:4 A. For those items, yes.	
327:17 - 328:7	<b>Prevoznik, Thomas 04-17-2019 (00:00:30)</b>	V1.73
	327:17 Q. Okay. Through ARCOS, can	
	327:18 DEA see the type of medication that's	
	327:19 being purchased?	
	327:20 A. Well, it's in there by NDC	
	327:21 number.	
	327:22 Q. Okay. And the NDC number	
	327:23 would -- would allow the DEA to determine	
	327:24 which product we are talking about?	
	328:1 A. Correct.	
	328:2 Q. So whether that was a -- the	
	328:3 DEA would know whether it was a oxycodone	
	328:4 5-milligram tablet, for example?	
	328:5 A. Correct.	
	328:6 Q. That level of detail?	
	328:7 A. Yes.	
329:3 - 329:19	<b>Prevoznik, Thomas 04-17-2019 (00:00:44)</b>	V1.74
	329:3 And through ARCOS, DEA can	
	329:4 see each and every bottle of opioids	
	329:5 that's transferred from a distributor to	
	329:6 a pharmacy for example, correct?	
	329:7 A. Correct.	
	329:8 Q. And they'll know the	
	329:9 location of that pharmacy?	
	329:10 A. Correct.	

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329:11 Q. Do they have the address for  
329:12 the pharmacy?

329:13 A. Yes. It's linked to the DEA  
329:14 registration.

329:15 Q. Okay. So through ARCOS, the  
329:16 DEA has precise information about how  
329:17 much of certain products is being shipped  
329:18 to which geographic areas, correct?

329:19 A. Correct.

334:13 - 335:16

**Prevoznik, Thomas 04-17-2019 (00:01:10)**

V1.75

334:13 Q. Okay. Getting back to the  
334:14 analysis of the ARCOS data. Is there a  
334:15 particular unit within DEA that's charged  
334:16 with analyzing ARCOS data?  
334:17 A. So there's actually two  
334:18 units. There's the input side. They  
334:19 actually deal with the down -- you know,  
334:20 upload from the registrants so there's  
334:21 constant communication with them whether  
334:22 regarding errors or, you know, trying to  
334:23 fix some of the data that was submitted.  
334:24 We don't change the data.

335:1 It's always the registrant has -- changes  
335:2 the data. We don't -- we don't change  
335:3 it.

335:4 And then the output side  
335:5 would be the targeting group. So there's  
335:6 QCs on the input side and there's also  
335:7 QCs on the out -- output side.

335:8 Q. With respect to the  
335:9 targeting group, what sort of analysis  
335:10 does it perform on the ARCOS data?

335:11 A. Trends. They support case  
335:12 investigations, doing charts, graphs.  
335:13 They'll -- they can show the comparison  
335:14 of what the national average is, what the  
335:15 state average and compare that with the  
335:16 registrant itself.

337:4 - 337:10

**Prevoznik, Thomas 04-17-2019 (00:00:19)**

V1.76

337:4 Q. Does the DEA use ARCOS data

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	337:5 to generate leads for investigations?	
	337:6 A. It can be.	
	337:7 Q. Without getting into any	
	337:8 details, can you think of occasions where	
	337:9 an analysis of ARCOS data led the DEA to	
	337:10 initiate an investigation?	
337:13 - 337:14	<b>Prevoznik, Thomas 04-17-2019 (00:00:02)</b>	V1.77
	337:13 THE WITNESS: So I could say	
	337:14 yes.	
362:15 - 362:23	<b>Prevoznik, Thomas 04-17-2019 (00:00:21)</b>	V1.78
	362:15 Q. But other than the two	
	362:16 letters from Mr. Rannazzisi, DEA did not	
	362:17 send any letters to registrants regarding	
	362:18 their obligation under the suspicious	
	362:19 order monitoring program, correct?	
	362:20 A. Written letters, correct.	
	362:21 Q. And DEA did not post any	
	362:22 guidance with respect to suspicious order	
	362:23 monitoring on its website, did it?	
363:2 - 364:3	<b>Prevoznik, Thomas 04-17-2019 (00:01:20)</b>	V1.79
	363:2 THE WITNESS: That's	
	363:3 correct.	
	363:4 BY MR. O'CONNOR:	
	363:5 Q. And DEA did not engage in	
	363:6 notice-and-comment rulemaking to provide	
	363:7 further guidance on suspicious order	
	363:8 monitoring to registrants, correct?	
	363:9 A. I am not -- I'm not in the	
	363:10 reg drafting section. So I don't know if	
	363:11 they -- the letter that we saw earlier	
	363:12 today, I'm not sure if that was --	
	363:13 Q. But since 1974 --	
	363:14 A. -- in there.	
	363:15 Q. I'm sorry.	
	363:16 But since 1974, DEA has not	
	363:17 promulgated any regulation providing	
	363:18 further guidance to registrants on the	
	363:19 supposed obligation to monitor and report	
	363:20 suspicious orders, correct?	
	363:21 A. Correct.	



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363:22	Q. With respect to suspicious	
363:23	order monitoring, does DEA agree that	
363:24	providing registrants with clear guidance	
364:1	is important?	
364:2	A. I think clear guidance is	
364:3	very important.	
392:4 - 392:6	<b>Prevoznik, Thomas 04-17-2019 (00:00:05)</b>	V1.80
392:4	Q. All right. DEA agrees that	
392:5	chronic pain is a serious problem for	
392:6	many Americans, true?	
392:9 - 392:17	<b>Prevoznik, Thomas 04-17-2019 (00:00:14)</b>	V1.81
392:9	THE WITNESS: Yeah, people	
392:10	have back pain.	
392:11	BY MR. STEPHENS:	
392:12	Q. And DEA also agrees that	
392:13	it's crucial for physicians who are	
392:14	engaged in legitimate pain treatment not	
392:15	to be discouraged from providing proper	
392:16	medication to patients as medically	
392:17	justified?	
392:21 - 393:3	<b>Prevoznik, Thomas 04-17-2019 (00:00:10)</b>	V1.82
392:21	THE WITNESS: Yes.	
392:22	BY MR. STEPHENS:	
392:23	Q. Okay. And DEA agrees that	
392:24	opioids, properly prescribed by DEA	
393:1	registered medical doctors, are an	
393:2	appropriate medication for many	
393:3	Americans?	
393:8 - 393:14	<b>Prevoznik, Thomas 04-17-2019 (00:00:11)</b>	V1.83
393:8	THE WITNESS: Yes.	
393:9	BY MR. STEPHENS:	
393:10	Q. DEA also agrees that there's	
393:11	a legitimate medical need under Title 21	
393:12	U.S.C. 801 for prescription opioids to	
393:13	treat pain in patients in the United	
393:14	States?	
393:17 - 393:18	<b>Prevoznik, Thomas 04-17-2019 (00:00:02)</b>	V1.84
393:17	THE WITNESS: For a	
393:18	legitimate medical purpose, yes.	
394:8 - 394:16	<b>Prevoznik, Thomas 04-17-2019 (00:00:21)</b>	V1.85

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394:8 Q. Okay. And DEA also agrees

394:9 that prescription opioids are necessary

394:10 to maintain the general welfare of

394:11 American people who need them?

394:12 A. Correct.

394:13 Q. Patients who are properly

394:14 prescribed opioid medications should be

394:15 able to obtain their medications from a

394:16 pharmacy?

395:4 - 395:4 **Prevoznik, Thomas 04-17-2019 (00:00:01)**

V1.86

395:4 THE WITNESS: Yes.

396:19 - 397:4 **Prevoznik, Thomas 04-17-2019 (00:00:17)**

V1.87

396:19 Q. Like manufacturers and

396:20 distributors, DEA also considers doctors

396:21 who prescribe opioids to their patients

396:22 to be registrants?

396:23 A. Correct.

396:24 Q. Okay. The prescribing

397:1 doctors have an obligation under the

397:2 Controlled Substances Act to prescribe

397:3 opioids responsibly so the controlled

397:4 substances will not be diverted, true?

397:6 - 397:6 **Prevoznik, Thomas 04-17-2019 (00:00:03)**

V1.88

397:6 THE WITNESS: Yes.

398:2 - 398:11 **Prevoznik, Thomas 04-17-2019 (00:00:18)**

V1.89

398:2 Q. Okay. But prescribers, not

398:3 manufacturers, distributors, or

398:4 pharmacists are required to have medical

398:5 degrees, right?

398:6 A. That's correct.

398:7 Q. Okay. And the physicians,

398:8 not manufacturers, distributors, or

398:9 pharmacists, are licensed to practice

398:10 medicine, right?

398:11 A. Correct.

401:5 - 401:9 **Prevoznik, Thomas 04-17-2019 (00:00:09)**

V1.90

401:5 Q. As to prescription

401:6 opioids, DEA believes that the

401:7 overwhelming majority of prescribing in

401:8 America is conducted responsibly?

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402:4 - 402:7	<p>401:9 A. Yes, correct.</p> <p><b>Prevoznik, Thomas 04-17-2019 (00:00:13)</b></p> <p>402:4 Q. The transcript is dated</p> <p>402:5 April 29, 2014. It's a subcommittee</p> <p>402:6 hearing on oversight investigations by</p> <p>402:7 the Committee of Energy and Commerce.</p>	V1.91
402:16 - 403:19	<p><b>Prevoznik, Thomas 04-17-2019 (00:00:54)</b></p> <p>402:16 Q. Page 76, Mr. Prevoznik. And</p> <p>402:17 we're looking at, like, the</p> <p>402:18 second-to-last paragraph where</p> <p>402:19 Mr. Rannazzisi is talking.</p> <p>402:20 Do you see that?</p> <p>402:21 A. Mm-hmm.</p> <p>402:22 Q. And there's a question from</p> <p>402:23 a Mr. Burgess ahead of that, correct?</p> <p>402:24 Do you see that?</p> <p>403:1 A. Yes.</p> <p>403:2 Q. Okay. And Mr. Burgess says</p> <p>403:3 something to the effect that</p> <p>403:4 Mr. Rannazzisi seems to imply that we are</p> <p>403:5 overprescribing. Mr. Rannazzisi then</p> <p>403:6 responds and says, "I think that if you</p> <p>403:7 are talking about 99.5 percent of the</p> <p>403:8 prescribers, no, they are not</p> <p>403:9 overprescribing. But our focus is in</p> <p>403:10 rogue pain clinics and rogue doctors who</p> <p>403:11 are overprescribing."</p> <p>403:12 Did I read that accurately?</p> <p>403:13 A. Yes.</p> <p>403:14 Q. Okay. So my question for</p> <p>403:15 you, the initial question was, DEA has</p> <p>403:16 publicly stated that 99.5 percent of the</p> <p>403:17 prescribers are not overprescribing,</p> <p>403:18 correct?</p> <p>403:19 A. Correct.</p>	V1.92
436:22 - 437:4	<p><b>Prevoznik, Thomas 04-18-2019 (00:00:19)</b></p> <p>436:22 Q. Okay. Now, more recently,</p> <p>436:23 in 2018, Mr. Patterson testified in front</p> <p>436:24 of Congress that 99.9 percent of doctors</p> <p>437:1 are all trying to do right by their</p>	V1.93

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	437:2 patients. Are you familiar with that?	
	437:3 A. Could I see the testimony?	
	437:4 Q. Sure.	
437:5 - 438:16	<b>Prevoznik, Thomas 04-18-2019 (00:01:16)</b>	V1.94
	437:5 (Document marked for	
	437:6 identification as Exhibit	
	437:7 DEA-Prevoznik-15.)	
	437:8 BY MR. STEPHENS:	
	437:9 Q. Mr. Prevoznik, I marked as	
	437:10 Exhibit Number 15 a hearing dated May 8,	
	437:11 2018, entitled "Challenges and Solutions	
	437:12 in the Opioid Crisis" before the	
	437:13 Committee of the Judiciary, House of	
	437:14 Representatives. I would direct you to	
	437:15 Page 32.	
	437:16 If you look at the top of	
	437:17 32, there's a paragraph that indicates	
	437:18 that Mr. Patterson is talking.	
	437:19 A. Correct.	
	437:20 Q. Do you see that?	
	437:21 A. Yes.	
	437:22 Q. Now, Robert Patterson in	
	437:23 2018 was the director -- I'm sorry, the	
	437:24 administrator of DEA?	
	438:1 A. Acting administrator.	
	438:2 Q. Acting administrator.	
	438:3 A. Right.	
	438:4 Q. It's the number one position	
	438:5 at DEA?	
	438:6 A. Correct.	
	438:7 Q. Okay. So here Mr. Patterson	
	438:8 was asked a question, and in part of his	
	438:9 response he says, "But I go back to the	
	438:10 fact that I look at the vast majority of	
	438:11 doctors, 99.99 percent are all trying to	
	438:12 do right by their patients."	
	438:13 Do you see that?	
	438:14 A. Correct.	
	438:15 Q. Did I read that accurately?	
	438:16 A. Yes.	

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442:20 - 442:21	<b>Prevoznik, Thomas 04-18-2019 (00:00:08)</b> 442:20 Q. In 2014, Mr. Rannazzisi 442:21 estimated 99.5 percent, right?	V1.95
443:3 - 443:3	<b>Prevoznik, Thomas 04-18-2019 (00:00:00)</b> 443:3 THE WITNESS: Correct.	V1.96
443:5 - 443:9	<b>Prevoznik, Thomas 04-18-2019 (00:00:08)</b> 443:5 Q. That's one-half of one 443:6 percent, right? 443:7 A. Correct. 443:8 Q. 2018, Mr. Patterson said 443:9 99.99 percent.	V1.97
443:12 - 443:14	<b>Prevoznik, Thomas 04-18-2019 (00:00:02)</b> 443:12 BY MR. STEPHENS: 443:13 Q. That's one-tenth of 1 443:14 percent, right?	V1.98
443:17 - 443:18	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b> 443:17 You can answer again. 443:18 THE WITNESS: Correct.	V1.99
462:20 - 463:2	<b>Prevoznik, Thomas 04-18-2019 (00:00:16)</b> 462:20 Q. If DEA headquarters does not 462:21 clearly communicate its interpretation of 462:22 the regulations and statutes related to 462:23 the suspicious order monitoring programs 462:24 to DEA's field offices, the field offices 463:1 may give inaccurate information to 463:2 registrants?	V1.100
463:6 - 463:18	<b>Prevoznik, Thomas 04-18-2019 (00:00:21)</b> 463:6 THE WITNESS: I don't -- I 463:7 don't know specifically what every 463:8 field office has provided that 463:9 guidance and oftentimes when there 463:10 is a question regarding that, we 463:11 will -- the field is instructed to 463:12 have the registrant reach out to 463:13 headquarters for an official 463:14 review. 463:15 BY MR. STEPHENS: 463:16 Q. Okay. 463:17 A. So the official review would 463:18 come from the headquarters side.	V1.101

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464:15 - 465:7	<b>Prevoznik, Thomas 04-18-2019 (00:00:39)</b> 464:15 Q. All right. So let's now 464:16 talk about communications between DEA and 464:17 the registrants. All right? 464:18 A. Yes. 464:19 Q. Okay. Agree that at some 464:20 point after -- well, let me strike that 464:21 and start over. 464:22 Mr. Rannazzisi ran the 464:23 diversion control group from 2006 to 464:24 about 2015, right? 465:1 A. Yes. That sounds about 465:2 right. 465:3 Q. Okay. After Mr. Rannazzisi 465:4 left DEA in 2015, DEA's leadership 465:5 recognized that it needed to make some 465:6 important changes to improve how DEA 465:7 communicated with registrants, true?	V1.102
465:12 - 466:15	<b>Prevoznik, Thomas 04-18-2019 (00:00:51)</b> 465:12 THE WITNESS: I mean, yeah, 465:13 yeah. 465:14 BY MR. STEPHENS: 465:15 Q. DEA's leadership after 465:16 Mr. Rannazzisi left DEA in 2015 wanted to 465:17 increase collaboration with registrants 465:18 to decrease diversion, correct? 465:19 A. Correct. 465:20 Q. DEA's current leadership has 465:21 acknowledged that it needs to do better 465:22 in its efforts to collaborate with 465:23 manufacturers, distributors, and retail 465:24 chain pharmacies, true? 466:1 A. I believe we all need to do 466:2 it. 466:3 Q. Okay. 466:4 A. Not just one. It's -- 466:5 everybody has to be involved. 466:6 Q. My question is maybe a 466:7 little bit different than your answer. 466:8 So let me restate it.	V1.103

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	466:9 A. Sure.	
	466:10 Q. DEA's current leadership has	
	466:11 acknowledged that it needs to do better	
	466:12 in its efforts to collaborate with	
	466:13 manufacturers, distributors and retail	
	466:14 chain pharmacies?	
	466:15 A. Correct.	
469:9 - 469:18	<b>Prevoznik, Thomas 04-18-2019 (00:00:21)</b>	V1.104
	469:9 Q. Okay. And would you agree	
	469:10 that current leadership at DEA is now	
	469:11 willing to collaborate with registrants	
	469:12 who can help DEA reduce diversion?	
	469:13 A. Yes.	
	469:14 Q. Fair to say that DEA's	
	469:15 current leadership understands that	
	469:16 treating potential good faith	
	469:17 collaborators as adversaries is not an	
	469:18 effective way to reduce diversion?	
469:21 - 469:21	<b>Prevoznik, Thomas 04-18-2019 (00:00:03)</b>	V1.105
	469:21 THE WITNESS: Correct.	
492:4 - 492:6	<b>Prevoznik, Thomas 04-18-2019 (00:00:09)</b>	V1.106
	492:4 Like internet pharmacies,	
	492:5 DEA -- DEA would agree that not all pain	
	492:6 clinics diverted controlled substances?	
492:9 - 492:16	<b>Prevoznik, Thomas 04-18-2019 (00:00:12)</b>	V1.107
	492:9 THE WITNESS: Correct.	
	492:10 BY MR. STEPHENS:	
	492:11 Q. Okay. There was some good	
	492:12 pain clinics who operated within the	
	492:13 boundaries of the law and there were some	
	492:14 rogue pain clinics that operated outside	
	492:15 the boundaries of the law.	
	492:16 Is that fair?	
492:20 - 492:20	<b>Prevoznik, Thomas 04-18-2019 (00:00:00)</b>	V1.108
	492:20 THE WITNESS: Yes.	
528:4 - 528:12	<b>Prevoznik, Thomas 04-18-2019 (00:00:22)</b>	V1.109
	528:4 Q. If a deputy administrator	
	528:5 who ran division control from 2006 to	
	528:6 2015 was concerned that suspicious order	
	528:7 report leads were being ignored by the	

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528:17 - 528:19	<p>528:8 field divisions, he could have assembled  528:9 a team of DEA's diversion investigators,  528:10 placed that squad at DEA headquarters  528:11 under his command to pursue those leads,  528:12 right?</p> <p><b>Prevoznik, Thomas 04-18-2019 (00:00:04)</b></p> <p>528:17 THE WITNESS: So he could  528:18 have done that. He didn't do it.  528:19 And we still haven't done it.</p>	V1.110
558:8 - 558:13	<p><b>Prevoznik, Thomas 04-18-2019 (00:00:14)</b></p> <p>558:8 Q. Between 2006 and 2015 under  558:9 Mr. Rannazzisi's leadership, did DEA have  558:10 a published policy that ensured that  558:11 someone at DEA would investigate every  558:12 suspicious order report that DEA  558:13 received?</p>	V1.111
558:16 - 558:17	<p><b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b></p> <p>558:16 THE WITNESS: Not that I'm  558:17 aware of.</p>	V1.112
897:10 - 897:14	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:15)</b></p> <p>897:10 Q. Okay. And I want to make sure  897:11 that your testimony is clear. When you say  897:12 whether a suspicious order is subjective, do  897:13 you mean that it varies from case to case, or  897:14 it depends on who's looking at it?</p>	V1.113
897:17 - 897:23	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:12)</b></p> <p>897:17 THE WITNESS: Both, really. It  897:18 depends who's looking at it and  897:19 what system do they have that's  897:20 triggering the suspicious order. So  897:21 it's whatever that registrant  897:22 designed, which is specific to that  897:23 registration.</p>	V1.114
1060:22 - 1061:1	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:11)</b></p> <p>1060:22 QUESTIONS BY MR. MAHADY:  1060:23 Q. Mr. Prevoznik, good afternoon.  1060:24 My name is Joe Mahady. I, along with my  1060:25 colleague, Robert Nicholas, are counsel for  1061:1 AmerisourceBergen in this litigation.</p>	V1.115
1070:8 - 1070:9	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b></p>	V1.116



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	1070:8 Q. Okay. I'm going to mark this	A2658.1
	1070:9 as Prevoznik 22.	
1071:14 - 1071:25	<b>Prevoznik, Thomas 05-17-2019 (00:00:20)</b>	V1.117
	1071:14 Q. Mr. Prevoznik, this morning	
	1071:15 Mr. Farrell asked you questions about	
	1071:16 documents that bear a US DEA Bates number,	
	1071:17 correct?	
	1071:18 A. Yes.	
	1071:19 Q. All right. And those are	
	1071:20 documents that the DEA has produced, correct?	
	1071:21 A. Correct.	
	1071:22 Q. Okay. And these were documents	
	1071:23 that were in the custody and control of the	
	1071:24 DEA, correct?	
	1071:25 A. Yes.	
1074:6 - 1075:22	<b>Prevoznik, Thomas 05-17-2019 (00:01:51)</b>	V1.118
	1074:6 Q. Mr. Prevoznik, can you please	
	1074:7 direct your attention to the bottom of this	
	1074:8 document?	
	1074:9 A. Yes.	
	1074:10 Q. And before we get there, I'm	
	1074:11 sorry, this document is dated what?	
	1074:12 A. July 23, 1998.	A2658.1.2
	1074:13 Q. And this document was sent to,	A2658.1.3
	1074:14 while the name is redacted, the regulatory	
	1074:15 compliance and security services of Bergen	
	1074:16 Brunswick Corporation; is that correct?	
	1074:17 A. Correct.	
	1074:18 Q. And it's signed, or stamped, by	A2658.1.4
	1074:19 Patricia M. Good, chief liaison and policy	
	1074:20 section; is that right?	
	1074:21 A. Yes.	
	1074:22 Q. Okay. Can you direct your	
	1074:23 attention to the bottom of the page below the	
	1074:24 section that has been redacted, and can you	
	1074:25 please read for me the subject line?	
	1075:1 A. "Approved suspicious order	A2658.1.5
	1075:2 monitoring system."	
	1075:3 Q. Okay. Now, if you can please	
	1075:4 read to me for the record the first sentence	A2658.1.6

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	1075:5 of the letter after "dear."	
	1075:6 A. "This is to grant approval of	
	1075:7 your request to implement on a nationwide	
	1075:8 basis your newly developed system to identify	
	1075:9 and report suspicious orders for controlled	
	1075:10 substances and regulated chemicals."	
	1075:11 Q. Okay. Can you -- so as	
	1075:12 required by the federal regulations, correct?	
	1075:13 A. Oh, I'm sorry, yes.	
	1075:14 Q. Okay. Can you read the next	
	1075:15 sentence, please?	A2658.1.7
	1075:16 A. "DEA managers who have been	
	1075:17 involved with the testing of the system have	
	1075:18 relied -- have relayed their positive	
	1075:19 opinions regarding its ability to provide	
	1075:20 information in a fashion which is not only	
	1075:21 useful overall but is also responsive to the	
	1075:22 needs of individual DEA offices."	
1079:17 - 1079:18	<b>Prevoznik, Thomas 05-17-2019 (00:00:11)</b>	V1.119
	1079:17 Q. Okay. I'm going to mark the	
	1079:18 next document as Prevoznik 23.	A781.9
1085:9 - 1088:13	<b>Prevoznik, Thomas 05-17-2019 (00:03:00)</b>	V1.120
	1085:9 Q. Mr. Prevoznik, can you please	
	1085:10 read the first paragraph of this letter --	
	1085:11 before we get there.	
	1085:12 Thomas Gitchel. Thomas Gitchel	A781.9.1
	1085:13 is identified as the chief liaison and policy	
	1085:14 section of the DEA, correct?	
	1085:15 A. Correct.	
	1085:16 Q. And he held that position in	
	1085:17 1996?	
	1085:18 A. Yes.	
	1085:19 Q. Now, if a registrant has	
	1085:20 questions about the regulation or the DEA's	
	1085:21 interpretation of the regulations, those	
	1085:22 questions are directed to the liaison and	
	1085:23 policy section of the DEA, correct?	
	1085:24 A. Correct.	
	1085:25 Q. And is the chief the	
	1086:1 highest-ranking member of that section?	

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1086:2 A. Yes.

1086:3 Q. Okay. This letter dated

1086:4 September 30, 1996, to Thomas Gitchel was

1086:5 sent by Chris Zimmerman of Bergen Brunswig.

1086:6 Do you know Chris Zimmerman?

1086:7 A. I know the name.

1086:8 Q. Okay.

1086:9 A. I don't know if we've ever met.

1086:10 Q. Okay. I want to start -- and

1086:11 I'll actually read the first paragraph for

A781.9.2

1086:12 purposes of time.

1086:13 "The purposes of this letter is

1086:14 to introduce the Drug Enforcement

1086:15 Administration to an innovative new system

1086:16 under development by Bergen Brunswig Drug

1086:17 Company to monitor and report customer orders

1086:18 of controlled substances which fit the

1086:19 suspicious order criteria outlined in 21 CFR

1086:20 1301.74(b)."

1086:21 Did I read that correctly?

1086:22 A. Yes.

1086:23 Q. Okay. And that is the section

1086:24 that we've been discussing today, right?

1086:25 A. Yes.

1087:1 Q. Okay. And that's the section

1087:2 that governs the reporting of suspicious

1087:3 orders?

1087:4 A. Yes.

1087:5 Q. Okay. Beginning with the next

A781.9.3

1087:6 sentence, "By way of background, as you know,

1087:7 BBDC participated in the development of a

1087:8 model excessive purchase report now in use by

1087:9 many distributor registrants."

1087:10 Were you aware that there was a

1087:11 model excessive purchase report that was

1087:12 being used by the registrants?

1087:13 A. A model? Yes.

1087:14 Q. Okay. It says, "As used by

A781.9.4

1087:15 BBDC, the excessive purchase report lists

1087:16 total customer purchases for the reported

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1087:17 month which exceed predetermined multiples of  
 1087:18 the average monthly purchase of BBDC's total  
 1087:19 customer base."

1087:20 Did I read that correctly?

1087:21 A. Yes.

1087:22 Q. Okay. So in describing the  
 1087:23 model excessive purchase report, it refers to  
 1087:24 customer purchases, correct?

1087:25 A. Yes.

1088:1 Q. And a monthly report, correct?

1088:2 A. Correct.

1088:3 Q. Okay. And it goes on to say at  
 1088:4 the end of that paragraph, "This report is  
 1088:5 produced in hard copy form monthly and is  
 1088:6 sent via certified mail to each DEA field  
 1088:7 office having responsibility for the  
 1088:8 reporting BBDC locations."

A781.9.5

1088:9 Did I read that correctly?

1088:10 A. Yes, you did.

1088:11 Q. And is that your understanding  
 1088:12 of how it worked?

1088:13 A. Yes.

1088:20 - 1090:1

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V1.121

A781.9.6

1088:20 Q. Next paragraph. "While  
 1088:21 feedback from DEA users over the years has  
 1088:22 generally confirmed our belief that the  
 1088:23 report standing alone is a useful law  
 1088:24 enforcement tool, BBDC suspicious order  
 1088:25 compliance program also involves the  
 1089:1 telephonic reporting of customer orders to  
 1089:2 DEA."

1089:3 Now, is it your understanding  
 1089:4 that DEA users did consider the excess  
 1089:5 purchase reports to be a useful law  
 1089:6 enforcement tool?

1089:7 A. Yes.

1089:8 Q. Okay. And is it your  
 1089:9 understanding that distributors like Bergen  
 1089:10 Brunswig also placed telephonic report --  
 1089:11 also performed telephonic reporting to the

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	1089:12 DEA for suspicious orders in the '90s?	
	1089:13 A. Yes, that's my understanding.	
	1089:14 Q. Okay. And it goes on to say	A781.9.7
	1089:15 that "in an average year, BBDC logs over	
	1089:16 12,000 telephone calls to DEA field offices	
	1089:17 nationwide to quarterly customer orders of	
	1089:18 controlled substances which it believes could	
	1089:19 fit the suspicious order criteria set forth	
	1089:20 in 1301.74(b)."	
	1089:21 Did I read that correctly?	
	1089:22 A. Yes.	
	1089:23 Q. And you have no reason to	
	1089:24 dispute the fact stated here that Bergen	
	1089:25 Brunswig was placing 12,000 calls to DEA	
	1090:1 field offices a year, do you?	
1090:4 - 1090:4	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	V1.122
	1090:4 THE WITNESS: No, I don't.	
1092:24 - 1093:2	<b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b>	V1.123
	1092:24 Q. So just to go back.	
	1092:25 DEA field offices could provide	
	1093:1 guidance to registrants about the suspicious	
	1093:2 order reporting requirements, correct?	
1093:4 - 1093:16	<b>Prevoznik, Thomas 05-17-2019 (00:00:33)</b>	V1.124
	1093:4 THE WITNESS: Yes.	
	1093:5 QUESTIONS BY MR. MAHADY:	
	1093:6 Q. Okay. And the DEA's	
	1093:7 expectation would be that the registrants	
	1093:8 listened to the guidance they were receiving	
	1093:9 from the field offices, correct?	
	1093:10 A. Yes.	
	1093:11 Q. Okay. And if a DEA field	
	1093:12 office told to -- advised a registrant to	
	1093:13 report a suspicious order in one form versus	
	1093:14 another, they should listen to that DEA field	
	1093:15 office, correct?	
	1093:16 A. Yes.	
1093:19 - 1094:1	<b>Prevoznik, Thomas 05-17-2019 (00:00:19)</b>	V1.125
	1093:19 Q. Now, the next sentence there,	A781.10.1
	1093:20 it says, "Some offices have diplomatically	
	1093:21 attempted to offer guidance as to the types	

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	1093:22 of orders that their offices would deem 1093:23 reportable in an effort to limit the number 1093:24 of telephone contacts." 1093:25 Did I read that correctly? 1094:1 A. Yes.	
1094:2 - 1094:5	<b>Prevoznik, Thomas 05-17-2019 (00:00:15)</b>	V1.126
	1094:2 Q. Are you aware that some DEA 1094:3 field offices in the '90s were trying to 1094:4 limit the number of suspicious orders being 1094:5 reported telephonically by the registrants?	
1094:11 - 1094:15	<b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b>	V1.127
	1094:11 THE WITNESS: I'm not 1094:12 personally aware of that. 1094:13 QUESTIONS BY MR. MAHADY: 1094:14 Q. Okay. But you have no reason 1094:15 to dispute the accuracy of that statement?	
1094:19 - 1094:19	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	V1.128
	1094:19 THE WITNESS: I don't.	
1095:1 - 1096:13	<b>Prevoznik, Thomas 05-17-2019 (00:01:22)</b>	V1.129
	1095:1 Q. Okay. "Against this backdrop, 1095:2 BBDC set to work on the development of a 1095:3 suspicious order reporting system that would 1095:4 provide better quality information to DEA in 1095:5 a more efficient manner." 1095:6 Did I read that correctly? 1095:7 A. Yes. 1095:8 Q. And you would agree with me 1095:9 that that's a laudable goal to have for a 1095:10 registrant? 1095:11 A. A lot of what? 1095:12 Q. That's something that a 1095:13 registrant should strive to do, is to provide 1095:14 better quality information to the DEA? 1095:15 A. Yes. 1095:16 Q. Okay. Now, I'm going to read 1095:17 the next paragraph, which describes the plan. 1095:18 "Our plan involves the creation 1095:19 of a computer program that compares a 1095:20 customer's controlled substance orders 1095:21 expressed in metric units of the active	A781.10.2
		A781.10.3

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	<p>1095:22 ingredient against a standard representing an</p> <p>1095:23 average of the customer's prior four months</p> <p>1095:24 of orders. Customers whose order exceed by a</p> <p>1095:25 specified percentage their prior four-month</p> <p>1096:1 average order history would be printed on a</p> <p>1096:2 summary report."</p> <p>1096:3 Did I read that correctly?</p> <p>1096:4 A. Yes.</p> <p>1096:5 Q. Okay. "BBDC's mainframe</p> <p>1096:6 computer in Orange, California, would</p> <p>1096:7 automatically fax this report simultaneously</p> <p>1096:8 to each respective DEA field office daily in</p> <p>1096:9 the early a.m. hours after the distribution</p> <p>1096:10 center has completed order processing</p> <p>1096:11 activities."</p> <p>1096:12 Did I read that correctly?</p> <p>1096:13 A. Yes.</p>	A781.10.4
1097:4 - 1097:20	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:53)</b></p> <p>1097:4 Q. "When DEA offices open each</p> <p>1097:5 day, the summary report would be waiting for</p> <p>1097:6 their review. DEA offices could also elect</p> <p>1097:7 to receive a month-end version of this report</p> <p>1097:8 via US mail. The summary report would show</p> <p>1097:9 the customer name, address, DEA number, item</p> <p>1097:10 description, NDC number, order date, active</p> <p>1097:11 ingredient volume ordered, active ingredient</p> <p>1097:12 shipped and customer allowance, i.e., average</p> <p>1097:13 of customer's prior four-month orders."</p> <p>1097:14 Did I read that correctly?</p> <p>1097:15 A. Yes.</p> <p>1097:16 Q. Now, what's contemplated here</p> <p>1097:17 in the summary report that would be faxed</p> <p>1097:18 daily to the DEA, so the DEA field offices</p> <p>1097:19 would have it in the morning, included active</p> <p>1097:20 ingredient shipped, correct?</p>	V1.130 A781.10.5
1097:23 - 1097:24	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b></p> <p>1097:23 THE WITNESS: It's what it</p> <p>1097:24 says.</p>	V1.131
1098:5 - 1098:9	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:08)</b></p> <p>1098:5 Q. Correct.</p>	V1.132



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1098:6	So these would be suspicious	
1098:7	orders that were reported to the DEA after	
1098:8	they had already been shipped, right?	
1098:9	A. Right.	
1099:8 - 1099:11	<b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b>	V1.133
1099:8	Q. Okay. But Bergen Brunswig is	
1099:9	specifically saying, "We're going to report	
1099:10	suspicious orders after they had already been	
1099:11	shipped," correct?	
1099:17 - 1099:20	<b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b>	V1.134
1099:17	Q. That's what they're proposing	
1099:18	to implement. That's all I'm trying to ask	
1099:19	you based off of this document.	
1099:20	A. Right, and --	
1100:1 - 1101:21	<b>Prevoznik, Thomas 05-17-2019 (00:01:46)</b>	V1.135
1100:1	Q. Okay. And your answer was	
1100:2	"right," that's your understanding of what	
1100:3	they're proposing?	
1100:4	A. That's my understanding of it,	
1100:5	yes.	
1100:6	Q. Okay. Next page. "Our intent	A781.11.1
1100:7	is to receive DEA's permission to replace our	
1100:8	current manner of daily suspicious order	
1100:9	reporting with the daily electronic facsimile	
1100:10	report," correct?	
1100:11	A. Yes.	
1100:12	Q. Okay. "We would like to have	A781.11.2
1100:13	DEA input on the final product because DEA	
1100:14	will be the primary users. One suggestion	
1100:15	would be to coordinate with one of your field	
1100:16	offices, perhaps the Los Angeles office, to	
1100:17	meet with our project development team."	
1100:18	Did I read that correctly?	
1100:19	A. Yes.	
1100:20	Q. Okay. It goes on to	A781.11.3
1100:21	say, "While your field office could beta test	
1100:22	the report and provide us with input on	
1100:23	aesthetics and content, there are some key	
1100:24	questions that DEA would need to provide	
1100:25	input on before the report is finalized. One	



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1101:1	question would be the assigned -- assignment	
1101:2	of the percentage value that a customer's	
1101:3	order would have to exceed before that order	
1101:4	would appear on the report."	
1101:5	Did I read that correctly?	
1101:6	A. Yes.	
1101:7	Q. Okay. And then it goes on to	
1101:8	say, "Tom, we are excited about the	A781.11.4
1101:9	opportunity to make constructive changes in	
1101:10	our suspicious order reporting system. By	
1101:11	working in a partnership with your office, we	
1101:12	can perhaps lead the way to developing a new	
1101:13	system that everyone feels good about."	
1101:14	Did I read that correctly?	
1101:15	A. Yes.	
1101:16	Q. Okay. And as the	
1101:17	representative from the DEA, was it your	
1101:18	understanding that Bergen Brunswig in 1996	
1101:19	was trying to work with the DEA as part of a	
1101:20	partnership to develop a system that everyone	
1101:21	could feel good about?	
1101:25 - 1102:4	<b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b>	V1.136
1101:25	THE WITNESS: Yes, that's what	
1102:1	it appears to be.	clear
1102:2	(Prevoznik Exhibit 26 marked	
1102:3	for identification.)	
1102:4	QUESTIONS BY MR. MAHADY:	
1102:5 - 1102:6	<b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b>	V1.137
1102:5	Q. Okay. I'm going to mark P,	
1102:6	Prevoznik 24 [sic].	D1922.1
1102:7 - 1102:15	<b>Prevoznik, Thomas 05-17-2019 (00:00:28)</b>	V1.138
1102:7	Okay. And there is a back.	
1102:8	A. Okay. Thank you.	
1102:9	Q. Okay. Again, this document has	
1102:10	a US DEA Bates number; is that correct?	D1922.1.1
1102:11	A. Yes.	
1102:12	Q. All right. So this document	
1102:13	was in the possession, custody and control of	
1102:14	the United States DEA, correct?	
1102:15	A. Correct.	

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1102:22 - 1102:24	<b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b>	V1.139
1102:22	Q. This document is dated	
1102:23	October 29, 1996, right?	D1922.1.2
1102:24	A. It looks like 1996.	
1103:4 - 1103:23	<b>Prevoznik, Thomas 05-17-2019 (00:00:47)</b>	V1.140
1103:4	Q. Okay. And that's just under	
1103:5	one month after Mr. Zimmerman sent his letter	
1103:6	describing the proposed program to Thomas	
1103:7	Gitchel; is that right?	
1103:8	A. Yes.	
1103:9	Q. Okay. And in the first	D1922.1.3
1103:10	paragraph of this letter which is sent to	
1103:11	Bergen Brunswig from Mr. Gitchel, he said	
1103:12	that "reference is made to your recent letter	
1103:13	in which you requested that Bergen Brunswig	
1103:14	be permitted to replace its current	
1103:15	telephonic reporting of suspicious orders	
1103:16	with a daily report transmitted by	
1103:17	facsimile."	
1103:18	Did I read that correctly?	
1103:19	A. Yes.	
1103:20	Q. Okay. So the DEA understood	
1103:21	that Bergen Brunswig was trying to replace	
1103:22	its daily suspicious order reporting with	
1103:23	this summary fax, right?	
1104:1 - 1104:6	<b>Prevoznik, Thomas 05-17-2019 (00:00:11)</b>	V1.141
1104:1	THE WITNESS: It looks like --	
1104:2	yes, so that's what it looks like, but	
1104:3	it -- because it's a daily report of	
1104:4	sales that have been commenced, it	
1104:5	would be the excessive purchase	
1104:6	reports.	
1105:4 - 1105:7	<b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b>	V1.142
1105:4	Q. But at least Bergen Brunswig	
1105:5	was saying to the DEA these are suspicious	
1105:6	orders that we're reporting, correct?	
1105:7	A. That's what it says, yes.	
1107:12 - 1108:12	<b>Prevoznik, Thomas 05-17-2019 (00:01:01)</b>	V1.143
1107:12	Q. Let's look at the DEA's	
1107:13	response. This is from the DEA. "Reference	

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	1107:14 is made to your recent letter in which you 1107:15 requested that Bergen Brunswick be permitted 1107:16 to replace its current telephonic reporting 1107:17 of suspicious orders with a daily report 1107:18 transmitted by facsimile." 1107:19 Okay? So the DEA is saying 1107:20 your request is to report your daily 1107:21 suspicious order reporting, correct? 1107:22 A. Correct.	
	1107:23 Q. Okay. The DEA goes on to say, 1107:24 "We have reviewed your proposal and feel that 1107:25 it could be a viable alternative to the 1108:1 current system. It is our understanding that 1108:2 a computer program has been created that can 1108:3 compare a customer's controlled substances 1108:4 orders to an average of the customer's order 1108:5 for the prior four months. Customer orders 1108:6 that exceed their four-month average order 1108:7 history by an as-yet unspecified percentage 1108:8 would be shown on a summary report that would 1108:9 be sent to the appropriate DEA field office 1108:10 on a daily basis." 1108:11 Did I read that correctly? 1108:12 A. Yes.	D1922.1.4
1109:6 - 1109:14	<b>Prevoznik, Thomas 05-17-2019 (00:00:19)</b> 1109:6 Q. "As proposed, the summary 1109:7 report would include the customer's name, 1109:8 address and DEA number, a description of the 1109:9 item ordered, the NDC number, date ordered, 1109:10 active ingredient volume ordered and shipped, 1109:11 and the customer's allowance on average -- or 1109:12 average order." 1109:13 Did I read that correctly? 1109:14 A. Yes.	V1.144 D1922.1.5
1109:24 - 1110:7	<b>Prevoznik, Thomas 05-17-2019 (00:00:21)</b> 1109:24 Q. Okay. Now, do you see anywhere 1109:25 in the first two paragraphs where the DEA 1110:1 clarifies that what you are proposing Bergen 1110:2 Brunswick is an excessive purchase reporting 1110:3 system, not a suspicious order reporting	V1.145 D1922.1.6

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	1110:4 system?	
	1110:5 A. No, I don't.	
	1110:6 Q. Okay. They -- the DEA says	D1922.1.8
	1110:7 suspicious order, right?	
1110:11 - 1110:15	<b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b>	V1.146
	1110:11 Q. The first sentence.	
	1110:12 A. Yes, it's reference to your	
	1110:13 letter.	
	1110:14 Q. Suspicious order?	
	1110:15 A. Yeah.	
1112:23 - 1113:10	<b>Prevoznik, Thomas 05-17-2019 (00:00:25)</b>	V1.147
	1112:23 Q. Okay. Now, the next -- the	
	1112:24 third paragraph. "We note that unlike the	D1922.1.7
	1112:25 program that generates Bergen Brunswig's	
	1113:1 monthly suspicious order report, the new	
	1113:2 program will compare the customer's order to	
	1113:3 his or her previous orders rather than to	
	1113:4 orders placed by other customers."	
	1113:5 Did I read that correctly?	
	1113:6 A. Yes.	
	1113:7 Q. Now, the DEA is the one	
	1113:8 referring to the monthly report as a	
	1113:9 suspicious order report, correct?	clear
	1113:10 A. Yes.	
1117:16 - 1117:21	<b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b>	V1.148
	1117:16 Q. Tom Gitchel, okay, he's the one	
	1117:17 that wrote this letter, right?	
	1117:18 A. Yes.	
	1117:19 Q. And at least to Tom Gitchel,	
	1117:20 Bergen Brunswig's monthly report was a	
	1117:21 suspicious order report?	
1117:24 - 1118:10	<b>Prevoznik, Thomas 05-17-2019 (00:00:22)</b>	V1.149
	1117:24 THE WITNESS: I'm not sure what	
	1117:25 Tom -- yeah.	
	1118:1 QUESTIONS BY MR. MAHADY:	
	1118:2 Q. But Tom refers to it as a	
	1118:3 monthly suspicious order report, correct?	
	1118:4 A. Right.	
	1118:5 Q. All right. And at least to Tom	
	1118:6 Gitchel, his understanding of what was being	

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	1127:19 THE WITNESS: From the various 1127:20 letters that you've given me, Bergen 1127:21 Brunswig came with a system that they 1127:22 wanted to show us, asked us for our 1127:23 input. So they showed us the design 1127:24 of what they were -- the design of the 1127:25 system that they were proposing to put 1128:1 nationwide.	
	1128:2 So we provided input. We	clear
	1128:3 tested it with them. So, yes.	
1129:6 - 1129:8	<b>Prevoznik, Thomas 05-17-2019 (00:00:12)</b>	V1.156
	1129:6 Q. Okay. And in designing it, the 1129:7 DEA provided input on the design, correct?	
	1129:8 A. Yes.	
1129:12 - 1129:13	<b>Prevoznik, Thomas 05-17-2019 (00:00:04)</b>	V1.157
	1129:12 Q. And the DEA tested the program, 1129:13 correct?	
1129:15 - 1129:20	<b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b>	V1.158
	1129:15 THE WITNESS: Yes.	
	1129:16 QUESTIONS BY MR. MAHADY:	
	1129:17 Q. And the DEA, based off of this 1129:18 document, was very pleased with how the 1129:19 suspicious order monitoring program was being 1129:20 run, correct?	
1129:23 - 1129:24	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	V1.159
	1129:23 THE WITNESS: That's what it 1129:24 appears from the letter.	
1134:20 - 1134:23	<b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b>	V1.160
	1134:20 Q. Now, we've seen at least two 1134:21 responses from DEA about the program. 1134:22 They're approving a suspicious order 1134:23 monitoring system, right?	
1135:2 - 1135:10	<b>Prevoznik, Thomas 05-17-2019 (00:00:14)</b>	V1.161
	1135:2 THE WITNESS: They're approving 1135:3 the system -- they're approving the 1135:4 implementation of the system that 1135:5 Bergen Brunswig designed. That's what 1135:6 they're approving. 1135:7 QUESTIONS BY MR. MAHADY: 1135:8 Q. Okay. We can go back to	

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	1135:9 Prevoznik 22, please.	A2658.1
	1135:10 A. 22.	
1135:11 - 1136:7	<b>Prevoznik, Thomas 05-17-2019 (00:01:08)</b>	V1.162
	1135:11 Q. Mr. Prevoznik, we've already	
	1135:12 looked at this document, but now that we've	
	1135:13 reviewed what the program consisted of, I	
	1135:14 just want to ask a couple follow-up	
	1135:15 questions.	
	1135:16 First sentence of this document	A781.1.1 - A2658.1.6
	1135:17 from Patricia Good, chief liaison and policy	
	1135:18 section, states, "This is to grant approval	
	1135:19 of your request to implement on a nationwide	
	1135:20 basis your newly developed system to identify	
	1135:21 and report suspicious orders for controlled	
	1135:22 substances and regulated chemicals as	
	1135:23 required by federal regulation."	
	1135:24 Correct?	
	1135:25 A. Correct, that's what it says.	clear
	1136:1 Q. And the subject of this	
	1136:2 document that was drafted by the DEA, within	
	1136:3 the possession, custody and control of the	
	1136:4 DEA and produced in [sic] the DEA in this	
	1136:5 litigation, is "approved suspicious order	
	1136:6 monitoring system"; is that correct?	
	1136:7 A. Yes, that's what it says.	
1139:10 - 1139:16	<b>Prevoznik, Thomas 05-17-2019 (00:00:26)</b>	V1.163
	1139:10 Q. Okay. Mr. Prevoznik, the DEA	
	1139:11 approved for implementation nationwide a	
	1139:12 suspicious order monitoring system that	
	1139:13 reported suspicious orders to the DEA on a	
	1139:14 daily basis after the report -- after the	
	1139:15 orders had already been shipped, correct?	
	1139:16 A. Yes.	
1140:12 - 1140:16	<b>Prevoznik, Thomas 05-17-2019 (00:00:12)</b>	V1.164
	1140:12 Q. Do you recall taking the	
	1140:13 training classes to the Bergen Brunswig,	
	1140:14 AmerisourceBergen distribution centers in	
	1140:15 Richmond, Virginia?	
	1140:16 A. Yes.	
1144:12 - 1144:14	<b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b>	V1.165



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1144:12 - 1144:16	<p>1144:12 Q. And that was valuable -- that</p> <p>1144:13 was, in fact, a valuable experience for your</p> <p>1144:14 diversion investigator trainees?</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b></p>	V1.166
1144:16 - 1144:21	<p>1144:16 THE WITNESS: Yes.</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b></p> <p>1144:18 Q. Okay. And AmerisourceBergen</p> <p>1144:19 partnered with you to provide that training,</p> <p>1144:20 right?</p> <p>1144:21 A. Yes.</p>	V1.167
1146:7 - 1146:9	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:08)</b></p> <p>1146:7 Do you recall DEA awarded</p> <p>1146:8 AmerisourceBergen a certificate of</p> <p>1146:9 appreciation in 2004?</p>	V1.168
1146:11 - 1146:14	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:03)</b></p> <p>1146:11 THE WITNESS: Yes.</p> <p>1146:12 QUESTIONS BY MR. MAHADY:</p> <p>1146:13 Q. Okay. And they were deserving</p> <p>1146:14 of that recognition?</p>	V1.169
1146:16 - 1146:16	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b></p> <p>1146:16 THE WITNESS: Yes.</p>	V1.170
1146:20 - 1146:24	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:21)</b></p> <p>1146:20 Now, fortunately for you, I do</p> <p>1146:21 want to revisit P22, which is the DEA</p> <p>1146:22 memorandum summarizing the distributor</p> <p>1146:23 initiative conference presentation with</p> <p>1146:24 AmerisourceBergen.</p>	V1.171
1149:14 - 1149:21	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:25)</b></p> <p>1149:14 Q. Okay. So at this meeting, the</p> <p>1149:15 DEA represented to Mr. Steve Mays of</p> <p>1149:16 AmerisourceBergen that if the DEA identified</p> <p>1149:17 a highly suspicious pharmacy to which</p> <p>1149:18 AmerisourceBergen was the wholesaler, it</p> <p>1149:19 would notify AmerisourceBergen via e-mail of</p> <p>1149:20 that pharmacy, correct?</p> <p>1149:21 A. That's what it says.</p>	V1.172
1151:5 - 1151:14	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:33)</b></p> <p>1151:5 Q. This one-and-a-half-page</p> <p>1151:6 summary of the meeting prepared by DEA about</p> <p>1151:7 the DEA's meeting with AmerisourceBergen,</p>	V1.173



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	1151:8 does it say in here, in this summary, 1151:9 anywhere, that the DEA advised 1151:10 AmerisourceBergen that it should not ship 1151:11 orders that it reports as suspicious in 1151:12 the -- I'm not talking about the 1151:13 presentation, we'll get to that in a second, 1151:14 but in the summary itself.	
1151:15 - 1151:15	<b>Prevoznik, Thomas 05-17-2019 (00:00:02)</b>	V1.174
	1151:15 A. No.	
1157:15 - 1157:18	<b>Prevoznik, Thomas 05-17-2019 (00:00:14)</b>	V1.175
	1157:15 Q. Okay. And the system that was 1157:16 designed, that the DEA approved to implement, 1157:17 using your words, had after-the-fact 1157:18 reporting, correct?	
1157:21 - 1157:21	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	V1.176
	1157:21 THE WITNESS: Yes.	
1167:16 - 1168:13	<b>Prevoznik, Thomas 05-17-2019 (00:00:54)</b>	V1.177
	1167:16 Q. Earlier today Ms. Singer showed 1167:17 you Diversion Investigator Manuals, correct? 1167:18 A. Yes. 1167:19 Q. You don't have to take them 1167:20 out. 1167:21 A. Okay. 1167:22 Q. I don't think so. 1167:23 Diversion Investigator Manuals, 1167:24 those are internal DEA documents, right? 1167:25 A. Yes. 1168:1 Q. Okay. And what's contained in 1168:2 the Diversion Investigator Manuals is not 1168:3 shared with the public, correct? 1168:4 A. Correct. 1168:5 Q. Okay. And so a registrant 1168:6 can't just go online and look up the DEA's 1168:7 Diversion Investigator Manuals from 1990, 1168:8 correct? 1168:9 A. Correct. 1168:10 Q. Okay. And so when those 1168:11 Diversion Investigator Manuals were in 1168:12 effect, AmerisourceBergen did not have a copy 1168:13 of that manual, right?	

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1168:16 - 1168:17	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 1168:16 THE WITNESS: Not to my 1168:17 knowledge.	V1.178
1205:1 - 1205:15	<b>Prevoznik, Thomas 05-17-2019 (00:00:31)</b> 1205:1 Q. And you were a diversion 1205:2 investigator until 2001? 1205:3 A. Well, I still think I am. 1205:4 Q. That's right. 1205:5 A. Still have the same job series. 1205:6 Q. Your primary duty was as a 1205:7 diversion investigator until 2001? 1205:8 A. Yes. 1205:9 Q. And in that situation, you were 1205:10 out in the field offices? 1205:11 A. Yes. 1205:12 Q. Okay. And you joined the 1205:13 Office of Diversion Control at headquarters 1205:14 in May 2012? 1205:15 A. I believe it was April.	V1.179
1206:6 - 1206:7	<b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b> 1206:6 Now, not every order of unusual 1206:7 size is indicative of diversion, correct?	V1.180
1206:10 - 1206:14	<b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b> 1206:10 THE WITNESS: Correct. 1206:11 QUESTIONS BY MS. MAINIGI: 1206:12 Q. There could be legitimate 1206:13 reasons for a pharmacy to place an order of 1206:14 unusual size, correct?	V1.181
1206:17 - 1206:20	<b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b> 1206:17 THE WITNESS: Correct. 1206:18 QUESTIONS BY MS. MAINIGI: 1206:19 Q. Can you think of any examples 1206:20 that come to mind for that, Mr. Prevoznik?	V1.182
1206:23 - 1207:1	<b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b> 1206:23 THE WITNESS: For which one? 1206:24 QUESTIONS BY MS. MAINIGI: 1206:25 Q. Why a pharmacy may place a 1207:1 larger than usual order.	V1.183
1207:6 - 1207:13	<b>Prevoznik, Thomas 05-17-2019 (00:00:24)</b> 1207:6 THE WITNESS: It could be a new	V1.184

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	1207:7 hospital opened, a new clinic opened. 1207:8 A. new hospice center could have 1207:9 opened. Any one of those. 1207:10 QUESTIONS BY MS. MAINIGI: 1207:11 Q. And, Mr. Prevoznik, not every 1207:12 order of unusual frequency is indicative of 1207:13 diversion, correct?	
1207:16 - 1207:20	<b>Prevoznik, Thomas 05-17-2019 (00:00:06)</b> 1207:16 THE WITNESS: Correct. 1207:17 QUESTIONS BY MS. MAINIGI: 1207:18 Q. There could be legitimate 1207:19 reasons for an order of unusual frequency, 1207:20 true?	V1.185
1207:23 - 1208:2	<b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b> 1207:23 THE WITNESS: True. 1207:24 QUESTIONS BY MS. MAINIGI: 1207:25 Q. Can you think of some examples 1208:1 as to why a pharmacy may place an order that 1208:2 is of unusual frequency?	V1.186
1208:7 - 1208:13	<b>Prevoznik, Thomas 05-17-2019 (00:00:17)</b> 1208:7 THE WITNESS: Again, it could 1208:8 be a new customer base, prescriber, a 1208:9 new doctor's office opened. 1208:10 That probably would be for a 1208:11 period of time, and then it would not 1208:12 keep going and going. It would level 1208:13 out at some point.	V1.187
1208:21 - 1208:24	<b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b> 1208:21 Q. Now, Mr. Prevoznik, not every 1208:22 order that deviates substantially from a 1208:23 normal ordering pattern is indicative of 1208:24 diversion, correct?	V1.188
1209:2 - 1209:7	<b>Prevoznik, Thomas 05-17-2019 (00:00:11)</b> 1209:2 THE WITNESS: Correct. 1209:3 QUESTIONS BY MS. MAINIGI: 1209:4 Q. And could there be legitimate 1209:5 reasons for an ordering pattern that is 1209:6 abnormal in some manner? 1209:7 A. Yeah, there could be.	V1.189
1212:13 - 1212:16	<b>Prevoznik, Thomas 05-17-2019 (00:00:12)</b>	V1.190

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1212:13 - 1212:19	<p>1212:13 Q. And I believe that you</p> <p>1212:14 indicated that there was not any sort of</p> <p>1212:15 requirement by the DEA of the maintenance of</p> <p>1212:16 due diligence files, correct?</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:02)</b></p>	V1.191
1213:21 - 1213:24	<p>1212:19 THE WITNESS: Yes.</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b></p> <p>1213:21 Are there -- are you aware of</p> <p>1213:22 DEA ever issuing any guidelines specific to</p> <p>1213:23 due diligence that describe how due diligence</p> <p>1213:24 should be conducted?</p>	V1.192
1214:2 - 1214:3	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:03)</b></p> <p>1214:2 THE WITNESS: No, not -- it's</p> <p>1214:3 the statute and the regulation.</p>	V1.193
1215:24 - 1216:2	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:11)</b></p> <p>1215:24 Q. So has the DEA ever issued any</p> <p>1215:25 guidance, Mr. Prevoznik, that serves as a</p> <p>1216:1 checklist, for example, of everything that</p> <p>1216:2 would go into effective controls?</p>	V1.194
1216:5 - 1216:12	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:19)</b></p> <p>1216:5 THE WITNESS: Not to my</p> <p>1216:6 knowledge.</p> <p>1216:7 QUESTIONS BY MS. MAINIGI:</p> <p>1216:8 Q. Coming back to the concept of</p> <p>1216:9 due diligence, the DEA has not issued any</p> <p>1216:10 guidance specifying how long a registrant</p> <p>1216:11 must hold on to due diligence, correct?</p> <p>1216:12 A. Correct.</p>	V1.195
1218:17 - 1218:23	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:19)</b></p> <p>1218:17 Q. The DEA has certainly never</p> <p>1218:18 issued any sort of guidance indicating that</p> <p>1218:19 registrants must hold on to due diligence</p> <p>1218:20 files for 15 years, correct?</p> <p>1218:21 A. Yes. The only guidance I know</p> <p>1218:22 is it's two years, two years for</p> <p>1218:23 recordkeeping for the registrant.</p>	V1.196
1219:1 - 1219:10	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:19)</b></p> <p>1219:1 Q. But there's no requirement that</p> <p>1219:2 a due diligence file even be maintained,</p> <p>1219:3 correct?</p>	V1.197

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	1219:4 A. Correct.	
	1219:5 Q. So the two-year rule does not	
	1219:6 apply to any due diligence files, per se,	
	1219:7 correct?	
	1219:8 A. Correct. I was just pointing	
	1219:9 out that within the regs, there is records	
	1219:10 for a two-year period.	
1220:20 - 1220:23	<b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b>	V1.198
	1220:20 Q. Is there any sort of	
	1220:21 requirement, either by the DEA or by the	
	1220:22 registrant, to hold on to an actual	
	1220:23 suspicious order being reported to the DEA?	
1221:1 - 1221:1	<b>Prevoznik, Thomas 05-17-2019 (00:00:02)</b>	V1.199
	1221:1 THE WITNESS: No.	
1221:2 - 1221:7	<b>Prevoznik, Thomas 05-17-2019 (00:00:18)</b>	V1.200
	1221:2 QUESTIONS BY MS. MAINIGI:	
	1221:3 Q. Has the DEA issued any sort of	
	1221:4 guidance indicating how long a suspicious	
	1221:5 order that's been reported must be	
	1221:6 maintained?	
	1221:7 A. No.	
1223:11 - 1223:14	<b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b>	V1.201
	1223:11 Q. And is it fair to say not every	
	1223:12 suspicious order that is reported to a	
	1223:13 regional office actually results in some sort	
	1223:14 of investigation?	
1223:17 - 1223:17	<b>Prevoznik, Thomas 05-17-2019 (00:00:00)</b>	V1.202
	1223:17 THE WITNESS: Yes.	
1232:21 - 1233:1	<b>Prevoznik, Thomas 05-17-2019 (00:00:18)</b>	V1.203
	1232:21 Q. Now, has DEA ever issued any	
	1232:22 sort of guidance or pronouncement essentially	
	1232:23 saying that you must -- as a distributor in	
	1232:24 that circumstance, you must terminate all	
	1232:25 future controlled substance sales to a	
	1233:1 customer if you report an order to the DEA?	
1233:5 - 1233:25	<b>Prevoznik, Thomas 05-17-2019 (00:00:36)</b>	V1.204
	1233:5 THE WITNESS: Well, it depends	
	1233:6 what they're -- what are they sending	
	1233:7 as the order. What is the order that	
	1233:8 they're saying is suspicious, correct?	

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	1233:9 QUESTIONS BY MS. MAINIGI:	
	1233:10 Q. Well, the distributor reports a	
	1233:11 suspicious order for customer X.	
	1233:12 A. Of what?	
	1233:13 Q. Of controlled substances.	
	1233:14 A. So they're reporting the entire	
	1233:15 order as being suspicious?	
	1233:16 Q. Correct.	
	1233:17 That's what they're obligated	
	1233:18 to do, correct? Right?	
	1233:19 A. Correct.	
	1233:20 Q. Okay. So they report a	
	1233:21 suspicious order to the DEA for customer X.	
	1233:22 Customer X may have other	
	1233:23 orders that are pending down the line.	
	1233:24 Should the distributor cut off all orders to	
	1233:25 customer X?	
1234:20 - 1235:3	<b>Prevoznik, Thomas 05-17-2019 (00:00:21)</b>	V1.205
	1234:20 A. So that registrant has made the	
	1234:21 decision -- has -- from their system they've	
	1234:22 deemed it a suspicious order. So they should	
	1234:23 not ship until -- if they choose to, if they	
	1234:24 want to alleviate that suspicion. If they	
	1234:25 choose not to, then they shouldn't ship.	
	1235:1 But if they choose to, then it	
	1235:2 becomes they need to look into it further to	
	1235:3 alleviate that suspicion.	
1236:2 - 1236:4	<b>Prevoznik, Thomas 05-17-2019 (00:00:03)</b>	V1.206
	1236:2 Q. Okay. But they could choose to	
	1236:3 ship it if they wanted to. That's a business	
	1236:4 judgment, right?	
1236:7 - 1236:9	<b>Prevoznik, Thomas 05-17-2019 (00:00:03)</b>	V1.207
	1236:7 THE WITNESS: They could ship	
	1236:8 it if they -- yeah, it's a business	
	1236:9 decision.	
1238:6 - 1238:11	<b>Prevoznik, Thomas 05-17-2019 (00:00:14)</b>	V1.208
	1238:6 Q. Are they required to hold the	
	1238:7 other orders that they don't view to be	
	1238:8 suspicious, or is it okay for the distributor	
	1238:9 in that instance to exercise their business	

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1238:10	judgment and send those nonsuspicious orders	
1238:11	out?	
1238:14 - 1238:20	<b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b>	V1.209
1238:14	THE WITNESS: Yes.	
1238:15	QUESTIONS BY MS. MAINIGI:	
1238:16	Q. Yes what?	
1238:17	A. They can.	
1238:18	Q. Okay. They can ship those	
1238:19	other orders out?	
1238:20	A. Yes.	
1239:18 - 1240:4	<b>Prevoznik, Thomas 05-17-2019 (00:00:37)</b>	V1.210
1239:18	Is it fair to say that DEA has	
1239:19	no internal policy defining the circumstances	
1239:20	under which a distributor is required to	
1239:21	terminate the distribution of controlled	
1239:22	substances to a pharmacy?	
1239:23	A. Yes.	
1239:24	Q. Now, do you recall being asked	
1239:25	last time a number of questions about the	
1240:1	NWDA suspicious order monitoring system? And	
1240:2	we may have even looked at it today.	
1240:3	Do you remember that?	
1240:4	A. Yes.	
1242:7 - 1242:17	<b>Prevoznik, Thomas 05-17-2019 (00:00:23)</b>	V1.211
1242:7	Q. So if we take a look at page 1	D1923.2
1242:8	of the NWDA document, Mr. Prevoznik --	
1242:9	A. Yes.	
1242:10	Q. -- second paragraph under	D1923.2.1
1242:11	background, could you read that out loud?	
1242:12	A. "The National Wholesale	
1242:13	Druggists' Association voluntarily began	
1242:14	working with the Department of Justice, Drug	
1242:15	Enforcement Administration, in establishing	
1242:16	controls clearly aimed at reducing or	
1242:17	eliminating illegal product distribution."	
1252:2 - 1253:14	<b>Prevoznik, Thomas 05-17-2019 (00:01:23)</b>	V1.212
1252:2	Q. Okay. So we just went over	
1252:3	this system that the DEA obviously had input	
1252:4	into that included two components, right?	
1252:5	A. Yes.	



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1252:6 Q. And the two components -- what

1252:7 was the first component?

1252:8 A. It was the after sales.

1252:9 Q. Okay. So the excessive

1252:10 purchase, right?

1252:11 A. Yes.

1252:12 Q. What was the second component?

1252:13 A. The -- let me check. The

1252:14 suspicious orders.

1252:15 Q. Right.

1252:16 So those are the two components

1252:17 of the NWDA system, right?

1252:18 A. Yes.

1252:19 Q. And the sentences that he's got

1252:20 after the one I asked you to read, he's

1252:21 essentially saying, doing the first doesn't

1252:22 relieve you of the obligation to do the

1252:23 second, right?

1252:24 A. Correct.

1252:25 Q. Okay. So read that sentence to

1253:1 me again that begins with "this system."

D1923.12.1

1253:2 A. "This system, as proposed, will

1253:3 meet the reporting requirements of 21 CFR

1253:4 1301.74."

1253:5 Q. And what is 1301.74(b) of 21

1253:6 CFR?

1253:7 A. Suspicious orders.

1253:8 Q. Okay. So Mr. Gitchel, who's

1253:9 acting chief of diversion operations, is

1253:10 saying in this letter that this two-component

1253:11 system that we've been discussing, as

1253:12 proposed, will meet the reporting

1253:13 requirements of suspicious orders, correct?

1253:14 A. That's what it says.

1253:19 - 1253:23 **Prevoznik, Thomas 05-17-2019 (00:00:29)**

V1.213

1253:19 Q. A distributor, Mr. Prevoznik,

1253:20 who in that time period followed this system

1253:21 that NWDA proposed, their system, at least,

1253:22 would be in compliance with 21 CFR

1253:23 1301.74(b), correct?



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1254:1 - 1254:7	<b>Prevoznik, Thomas 05-17-2019 (00:00:26)</b> 1254:1 THE WITNESS: Yes, but this 1254:2 date is 1984. You've been asking me 1254:3 1996 to 2006, so -- so, yeah, 1984. 1254:4 QUESTIONS BY MS. MAINIGI: 1254:5 Q. Do you -- are you aware of any 1254:6 communication by Mr. Gitchel subsequently 1254:7 that overruled his statements?	V1.214  clear
1254:9 - 1254:16	<b>Prevoznik, Thomas 05-17-2019 (00:00:20)</b> 1254:9 THE WITNESS: Not to my 1254:10 knowledge. 1254:11 QUESTIONS BY MS. MAINIGI: 1254:12 Q. Now, in this letter that 1254:13 Mr. Gitchel wrote, he doesn't say anything 1254:14 about halting shipment of excessive or 1254:15 suspicious orders, right? 1254:16 A. No.	V1.215
1261:3 - 1261:15	<b>Prevoznik, Thomas 05-17-2019 (00:00:30)</b> 1261:3 Do you recall from the time 1261:4 period of about 2007 to 2013, DEA did not 1261:5 want to sit down with HDMA to provide them 1261:6 with guidance or guidelines related to an 1261:7 adequate suspicious order monitoring system? 1261:8 A. Yes. 1261:9 Q. "Yes" meaning they did not want 1261:10 to sit down with HDMA? 1261:11 A. Right. 1261:12 Q. Whereas in the late '90s, we 1261:13 saw that they were willing to sit down with 1261:14 HDMA, right? 1261:15 A. Correct.	V1.216

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